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FACTORS CONTRIBUTING TO HIGH DEFAULTERS AMONG PATIENTS ON ANTIRETROVIRAL DRUGS IN BEREA DISTRICT, LESOTHO

A mini dissertation presented to the

Faculty of Health Sciences,

University of Johannesburg,

In partial fulfilment of Master of Public Health

By

Limakatso Lebelo

(Student number: 218100043)

Supervisor: _____ **18/02/2021**

Prof S. A. Feresu **Date**

Declaration

I declare that this dissertation is my own, unaided work. It is being submitted for the Master of Public Health degree at the University of Johannesburg. It has not been submitted before for any degree or examination at any other University.

17-02-2021

(Signature) Date

18-02-2021

Prof S.A. Feresu Date

Dedication

I dedicate this piece of work to my entire family for their undying support during the time of studies. I especially feel honoured to have such a strong social support. I specifically dedicate it to my son, Tumi, whom I did not have much time to even help him with his schoolwork or listen to his stories after school. He has been so patient with me and I love him so much. God bless you all.

Acknowledgements

I would like to acknowledge my supervisor, Prof S. Feresu, you have been more than a supervisor or facilitator to me, you were like a real mother, always giving guidance and encouragement when things were tough and seemed impossible especially during ethics evaluation and throughout the whole learning process. Words cannot express my gratitude for having such a wonderful dedicated supervisor.

Secondly, I would like to acknowledge the Ministry of Health, Lesotho for allowing me to conduct this study and the two health facilities, Berea Hospital and Holy Family Health Centre staff members for welcoming and accommodating me while assisting me with all the documents I needed.

Lastly, I would like to acknowledge my boss, who in the first place pushed me out of my comfort zone and directed me in the right direction to further my studies and offered me support.

Abstract

Background: To achieve sustainable development goal 3, Lesotho is striving to scale up ART coverage and increase retention to care and treatment for all HIV positive patients initiated on ART. However, high defaulter rate is still a problem and barrier to successful ART scale up implementation. Evidence shows that defaulter or lost to follow-up is a real problem requiring further investigation. The study seeks to explore possible causes and contributing factors of default among patients initiated on ART from 2016-2017 in two Berea District health facilities.

Methods: An unmatched Case-Control Study design was adopted. Secondary data from the patients' medical records of 2016 to 2017 was used. The data collection was done from the secondary data sources; ART register and ART care card using a pre-coded questionnaire in the form of data abstraction form. The results of this study are based on the frequency distributions and the logistic regression analysis that was performed on the data.

Results: Patients below 30 years contributed 31% of the total participants and constituted 44.9% of all cases in the study. There were more female than male participants, accounting for 65.6% of total participants. Age group below 30 years was less likely associated with ART default (crude odd ratio, 4.86; 95% cl, 2.75-8.58. Adjusted odds ratio, 0.45, 95% cl, 0.23-089; p= 0.021). Being widowed was more likely associated with ART default (adjusted odds ratio, 2.81, 95% cl, 1.29-6.14 and p= 0.009). Being unemployed was more likely associated with ART default (adjusted odds ratio, 1.81, 95% cl 1.09-2.98 and p= 0.021). While self-employment was less likely associated with ART default (adjusted odds ratio, 0.21, 95% cl 0.10-0.42 and p<.001). Patients with primary education were less likely to default ART (adjusted odd ratio, 0.34, 95% cl 0.16-0.72 and p=0.005).

Conclusion: This evaluation has revealed factors associated with ART default for patients enrolled into care and initiated on ART. The findings of this study could assist policymakers and authorities to develop innovative approaches to ensure treatment adherence and retention among HIV positive patients enrolled into care and treatment. Some findings were surprisingly inconsistent with the existing body of knowledge. For instance, the study revealed that younger age group are more likely to adhere to treatment than older age. It is important to note that spousal support is one of the factors that was found to be directly linked to ART adherence. The factors that were identified as associated with ART default can be easily mitigated as they do not need extra resources. Health care workers have to implement client-centred approach

and create an enabling environment for patients to make decisions based on their treatment needs and lifestyle.

Keywords: Adherence, Antiretroviral therapy, ART Default, HIV positive, Initiation.

Table of Contents

List of Tables

List of Figures

LIST OF ABREVIATIONS

AIDS -	Acquired Immune Deficiency Syndrome
ART -	Anti-Retroviral Therapy
ARV-	Anti Retro Viral
DTG-	Dolutegravir
EFV-	Efavirenz
HAART-	Highly Active Anti-Retroviral Therapy
HIV -	Human Immunodeficiency Virus
LePHIA-	Lesotho Population–Based HIV Impact Assessment
LTFU -	Lost to Follow Up
MOH-	Ministry of Health
NNRTI-	Non-nucleoside reverse transcription inhibitor
PI-	Protein inhibitor
PLWHA -	People Living with HIV and AIDS
TB –	Tuberculosis
UTT-	Universal Test and Treat
WHO -	World Health Organisation

DEFINATION OF TERMS or GLOSSARY

Active patient-	A patient who has been registered and receives regular ART at a given facility
Adherence -	For the purposes of this study, this refers to the extent to which patients follow the instructions of their health care providers with regard to taking their medicines
ART regimen: First line	The initial combination of antiretroviral drugs prescribed for an eligible HIV-infected patient who has not taken any ARV drugs before
ART regimen: Second line	The combination of antiretroviral drugs prescribed for a patient after the 1st line regimen fails to suppress HIV replication
Defaulter	A patient who has not attended the ART clinic or pharmacy for more than 7 days but less than 90 days
Immunological failure	CD4 count falls to the baseline (or below) or Persistent CD4 levels below 100 cells/mm.
Lost to follow up patient	A patient who has not attended the ART clinic or pharmacy for more than 90 days since the last scheduled appointment and whose whereabouts are unknown to the clinic staff
Virological failure	Plasma viral load above 1000 copies/ ml based on two consecutive viral load measurements after 3 months, with adherence support

CHAPTER ONE: INTRODUCTION

1.0 Introduction

Globally, Lesotho ranks second in HIV prevalence. Prevalence rates vary among Lesotho's 10 districts and range from 17.8% in Butha-buthe to 29.3% in Mohale's hoek, and Berea prevalence was reported as 23% (LePHIA, 2017). In June 2016, per the new Universal Test and Treat (UTT) guidelines released by the World Health Organization (WHO), Lesotho became the first African country to implement UTT guidelines. While these guidelines removed all restrictions to antiretroviral therapy (ART) initiation for HIV-affected people, actual ART coverage remained at 41% for adults and 40% for children. Many facilities face a backlog of patients now eligible for treatment, and many patients face access challenges, in part due to Lesotho's mountainous terrain and incomplete road system (Usaidassist.org, 2018).

In an effort to achieve the United Nations Sustainable development goal 3, that is, good health and wellbeing and attain epidemic control by reaching 90-90-90 target, Lesotho is striving to scale up ART coverage and increase retention to care and treatment for all HIV positive patients initiated on ART. In LePHIA (2017) final report, Lesotho achieved the second and nearly achieved the third of the 90-90-90 targets: 90.2% of HIV-positive adults ages 15-59 years who knew their status reported ART use, and 88.3% of those on ART had viral load suppression. Retention in to care and or ART adherence contribute to the third 90 as viral load suppression can only be attained with good treatment adherence and retention into care. ART is a lifelong commitment that requires patients to adhere diligently to daily medication dosing schedules and make frequent clinic visits for care. Patients who discontinue treatment are at high risk of illness and death because of AIDS-related conditions. Consequently, many studies have attempted to quantify and ascertain the status of patients reported as lost to follow-up. However, high defaulter rate is still the problem and a barrier to successful ART scale up implementation. In recent years an increasing body of evidence, including two systematic reviews, has shown low retention in care of patients starting ART in sub-Saharan Africa. Early life losses after the initiation of ART have been recognized as important barriers to the success of ART programs in resource-constrained settings (Honge et al.,2013).

According to Lesotho's 2015 UNAIDS Progress Report, the proportion of people retained on ART after 12 months ranges between 70% and 80%, this means that there are 20-30% defaulter rates in patients initiated on ART within the first year (AVERT, 2018). It is also documented that defaulter

are high in the first 3 years of ART (Pepfar.gov., 2019). Previous studies have identified several possible reasons for defaulting from treatment programmes.

The objective of the study is to better understand the reasons why patients default from antiretroviral treatment (ART) programmes to help design interventions that improve treatment retention and ultimately, patient outcomes. This study aims to gain more insight into the reasons why patients default from treatment programmes, the contributing factors, and suggest actionable interventions to improve retention by conducting a case control study in two Berea District health facilities using a cohort of patients enrolled on ART from 2016 to 2017.

1.1 Background

Following the implementation of Test and Treat in Lesotho in 2016, it is anticipated that patients' retention into care and treatment might be a problem as this is the new concept of initiating people on ART regardless of their virological and immunological status. These are people who mostly are not sick and still look healthy therefore initiating a life-long treatment does not make much sense to them. In the old guidelines before test and treat, HIV positive patient were initiated on ART based on whether they meet eligibility criteria as shown in Figure 1, Diagram A below. Post-test and treat, there was a transition from the old guidelines whereby all HIV positive patients were initiated on ART regardless of their immunologic or clinical status as shown in Diagram B below.

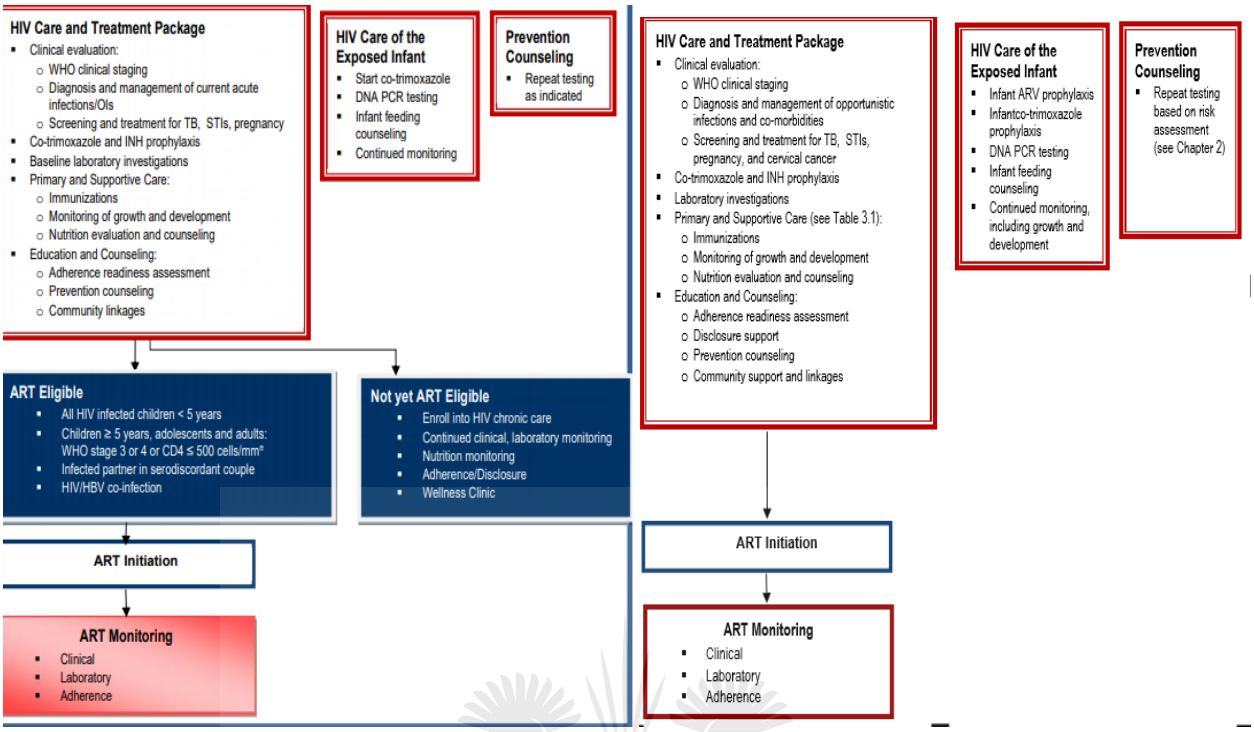

Diagram A **Diagram B**

Figure 1: ART initiation flow diagram before and after test and treat

Source: MOH ART guidelines

Early losses after the initiation of ART have been recognized as important barriers to the success of ART programs in resource-constrained settings. It was found that on average 21% of patients had been lost to programmes in the first six months after starting ART (Pepfar.gov., 2019). Similarly, a systematic review of ART programmes in sub-Saharan Africa found that about 40% of patients were lost at two years, with large variation in retention rates between programmes (Brinkhof, Pujades-Rodriguez and Egger, 2009). In another study titled 'Outcomes of antiretroviral treatment programmes in rural Southern Africa' it was found that 5.8% did not return after initiation of ART. Over 9.6% of those with at least one follow-up visit died and 18.1% were lost to follow-up. At 3 years the cumulative incidence of death and lost to follow up (LTFU) were 12.5% (11.5–13.5%) and 25.4% (24.0–26.9%), respectively (Wandeler et al., 2018). In a study on access to HIV care and treatment for migrants between Lesotho and South Africa, it was documented that default rates were significantly higher in urban areas compared to rural areas, 28.3% versus 18.4%, $p = 0.011$ (Faturiyele et al., 2018).

Recent systematic reviews and meta-analysis conducted by WHO have shown that Dolutegravir (DTG) based regimens are better tolerated and tend to be protective against treatment discontinuation due to adverse events when compared with Efavirenz (EFV 600). Among stable, virologically suppressed patients on non-nucleoside reverse transcription inhibitor (NNRTI) or protease inhibitor-based first-line antiretroviral treatments, substitution with a DTG-containing regimen was also well-tolerated and non-inferior in maintaining viral suppression, with high rates of satisfaction compared to those remaining on their existing regimen. Furthermore, DTG is associated with a more rapid viral suppression and higher genetic resistance barrier, when compared with NNRTIs (WHO, 2011).

According to URC (2020), Lesotho Ministry of Health has therefore been rolling out DTG use among stable ART clients as well as clients initiating ART. All clients who have undetectable viral load on NNRTI or PI-based regimens initiated prior to the introduction of DTG should have the PI or NNRTI substituted for DTG unless DTG is contraindicated. In this study, attention was given to patients who initiated ART after implementation of Test and Treat to assess their retention and learn more about barriers to retention on treatment.

1.2 Problem statement

To achieve millennium development goal 6, Lesotho is striving to scale up ART coverage and increase retention to care and treatment for all HIV positive patients initiated on ART. However, high defaulter rate is still the problem and a barrier to successful ART scale up implementation. In recent years an increasing body of evidence, including two systematic reviews, has shown low retention in care of patients starting ART in sub-Saharan Africa. Early losses after the initiation of ART have been recognized as important barriers to the success of ART programs in resource-constrained settings. It was found that on average 21% of patients had been lost to programmes in the first six months after starting ART. Similarly, a systematic review of ART programmes in sub-Saharan Africa found that about 40% of patients were lost at two years, with large variation in retention rates between programmes (Brinkhof, Pujades-Rodriguez and Egger, 2009). These previous studies show that defaulter or lost to follow-up is a real problem which requires investigation of the possible causes and contributing factors. There are many possible contributing factors that may affect patient's adherence to treatment and lead to possible lost to follow-up or

default. The study sought to explore possible causes of default among patients initiated on ART from 2016-2017 in two Berea District health facilities.

1.3 Aim and objectives

1.3.1 Research overall objective

The overall objective of this study was to determine factors contributing to high defaulters for patients on antiretroviral drugs in Berea district; Lesotho, registered from June 2016 to June 2017. The ultimate goal of this study was to determine those factors contributing to ART defualt for ART patients and help the HIV program to develop interventions that are patient-centered and help to improve adherence to ART, subsequently improving patients' health outcomes. The objective was framed to answer the research questions below.

1.3.2 Research questions

1. What is the prevalence of defaulting to antiretroviral treatment for patients in Berea district?
2. Is there a relationship between socio-demographic, occupational, patient related and health system factors and defaulting to ART for patients in Berea district?
3. Is there a relationship social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017?

1.3.3 Specific objectives

1. To assess the prevalence of defaulting for patients on ART at Berea district.
2. To assess if there is a relationship between defaulting to ART for patients in Berea district and socio-demographic, occupational, patient related and health system factors.
3. To examine if there a relationship social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

1.4 Hypothesis

1.4.1 Null hypothesis:

There exist no factors that significantly contribute to patients defaulting antiretroviral treatment at Berea District. Patients defaulting ART cannot be linked to factors around them. There is no association between patients' related factors, occupational or health system and defaulting to

antiretroviral treatment. Patients' defaulting to ART is merely by chance not necessarily linked to any of the factors around them.

1.4.2 Alternative hypothesis

Patients' defaulting to antiretroviral treatment in Berea District is directly linked to a variety of factors. Factors such as patients related factors, socio-demographic factors, health system and cultural factors may affect patients' defaulting to ART. A patient who is from poor social background and uninformed is more likely to default ART than a patient who is from a good background who is well informed.

1.4.3 The specific research hypotheses

1. To assess the prevalence of defaulting for patients on ART at Berea District.

   H0: The prevalence of defaulters for patients on ART at Berea District is not different from the general population in Lesotho

   HA: There is significantly high prevalence of defaulters for patients on ART at Berea District compared to the general population in Lesotho.

2. To assess if there is a relationship between defaulting to ART for patients in Berea District and socio-demographic, occupational, patient related and health system factors.

   H0: There is no association between defaulting to ART for patients in Berea District and socio-demographic, occupational, patient related and health system factors.

   HA: There is an association between socio-demographic, occupational, patient related and health system factors and defaulting to ART for patients in Berea District.

3. To examine if there a relationship social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

H0: There is no association between social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

HA: There is an association between social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

1.4 Feasibility of the study

The study was feasible technically as the data collection involved abstraction from patients' records which were readily available from the same cohort and it included both adherent and non-adherent patients for comparison. Financially, there was no requirement for provision of financial resources as the materials needed were readily available and the study sites were all within reach for the researcher. Furthermore, the study was feasible both legally and ethically as there were no adverse effects that could happen to the participants or anything that could pose danger (Bonita et al,2015).

1.5 Purpose and importance of the study

The purpose of this study was to obtain an understanding of the factors that contribute to treatment defaulting amongst HIV positive patients who are enrolled in the ART treatment programme in two health facilities of Berea District, Lesotho. Variables measured included independent variables of ART treatment defaulters and dependent variables that included socio-demographic factors leading to ART treatment defaulting, patient's health status related factors leading to ART treatment default, service-related factors leading to ART treatment default and treatment related issues contributing to ART treatment default. The findings can assist policymakers and authorities to develop innovative approaches to ensure treatment adherence and retention among HIV positive patients enrolled into care and treatment.

1.6 Significance of the study

The significance of the study on factors contributing to high defaulter rate in patients on ART was to bridge the knowledge gap between what is theory and what is happening in practice. It is reported that patients' adherence to treatment has improved over the years with increasing knowledge and reduction of stigma but on the ground many patients are still defaulting treatment.

The findings of the study can significantly help in planning and implementing the future strategies for improving patients' retention into care, reducing treatment defaulters and may invite interested bodies for further wide scale investigations. National guidelines and policy on ART initiation may also be improved based on the findings of the study on solutions for defaulter rates. Moreover,

exploring and learning more about factors contributing to high defaulter rate can benefit the national HIV programme as it assesses and implements solutions to identified problems and improved patient outcomes. Patients can also benefit as new strategies to support their adherence are identified from their perspective and point of view which is more patient-centred than programme-centred. The findings can also benefit clinicians and healthcare workers on the ground as they will now have a better understanding of patients' needs and the support needed for treatment adherence.

1.7 Delimitation

This study was about factors that contribute to high defaulter rate for patients on ART treatment in Berea District. The study was conducted in two Berea health facilities because of limited resources. It involved patients' records review for all patients registered in two health facilities from January 2016 to December 2017. The target population was both males and females older than 18 years of age. All patients who were on ART and were above 18 years of age were included in the study if they met the eligibility criteria.

1.8 Summary and transition

Chapter One of this study on factors contributing to high defaulter rate of ART patients in Berea District, Lesotho introduced and gave the background information to the study putting in context how it came about. Following the implementation of Test and Treat in Lesotho in 2016, it is anticipated that patients' retention into care and treatment might be a problem as this is the new concept of initiating people on ART regardless of their virological and immunological status. These are patients who are mostly not sick and still look healthy therefore initiating on a life-long treatment might not make much sense to them.

Kassahun and Zalalem (2018) reported that early losses after the initiation of ART have been recognized as important barriers to the success of ART programmes in resource-constrained settings. In view of the background, the statement of the problem was formulated. The significance, rationale and purpose of the study were established. The findings of the study will significantly help in planning and implementing the future strategies for improving patients' retention into care, reducing treatment defaulters and may invite interested bodies for further wide scale investigations and thus this study is to bridge the knowledge gap and find possible solutions to patients' non-adherence to ART. Hence, the purpose of this study was to obtain an under-

standing of the factors that contribute to treatment defaulting amongst HIV positive patients who were enrolled in the ART treatment programme in two health facilities of Berea District, Lesotho.

Research questions and specific objectives of the study were formulated, and the study hypothesis, which stated that there exist no factors that significantly contribute to patients defaulting antiretroviral treatment at Berea District, Lesotho. Patients defaulting ART cannot be linked to factors around them. In order to inform interventions and programmatic decisions that will achieve significant reductions in patient defaulting ART, local studies are needed.

CHAPTER TWO: LITERATURE REVIEW

2.1 The conceptual framework

The Health Belief Model (HBM) is a psychological health behaviour change model developed to explain and predict health-related behaviours, particularly regarding the uptake of health services. The Health Belief Model was first developed in the 1950s by social psychologists Godfrey Hochbaum, Irwin Rosenstock and Stephen Kegels working in the U.S. Public Health Services and remains one of the best known and most widely used theories in health behaviour research. The HBM suggests that people's beliefs about health problems, perceived benefits of action and barriers to action and self-efficacy explain engagement (or lack of engagement) in health-promoting behaviour. A stimulus, or cue to action, must also be present in order to trigger the health-promoting behaviour (En.wikipedia.org, 2018).

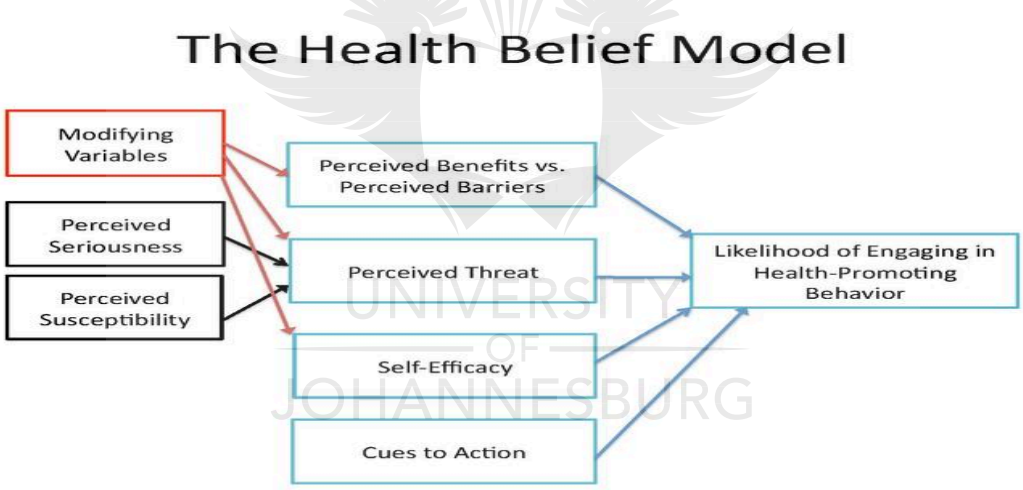

Figure 2: Health Belief Model

Source: Share Alike 3.0

The Health Belief Model (HBM) was identified as the conceptual framework for this study. The Health Belief Model (HBM) is one of the most widely used conceptual frameworks for understanding health behaviour. The HBM is based on the understanding that a person will take a health-related action. The Health Belief Model is a framework for motivating people to take positive health actions that uses the desire to avoid a negative health consequence as the prime

motivation. For example, high viral load is a negative health consequence, and the desire to avoid immune suppression and high viral load can be used to motivate HIV positive patients to adhere to treatment. That is adherence to treatment is possible if the patient feels that the negative heath condition (immune suppression, high viral load) can be avoided, then the patient will have a positive expectation that by adhering to antiretroviral treatment, he/she will avoid immune suppression. If the patient believes that she/he can successfully take a recommended health action that is he/she can take antiretroviral treatment comfortably and with confidence. The HBM is relevant for this study, because the underlying concept is that health behaviour (defaulting antiretroviral treatment) is determined by personal beliefs or perceptions about a disease and strategies to decrease its occurrence (Ali, 2002:33).

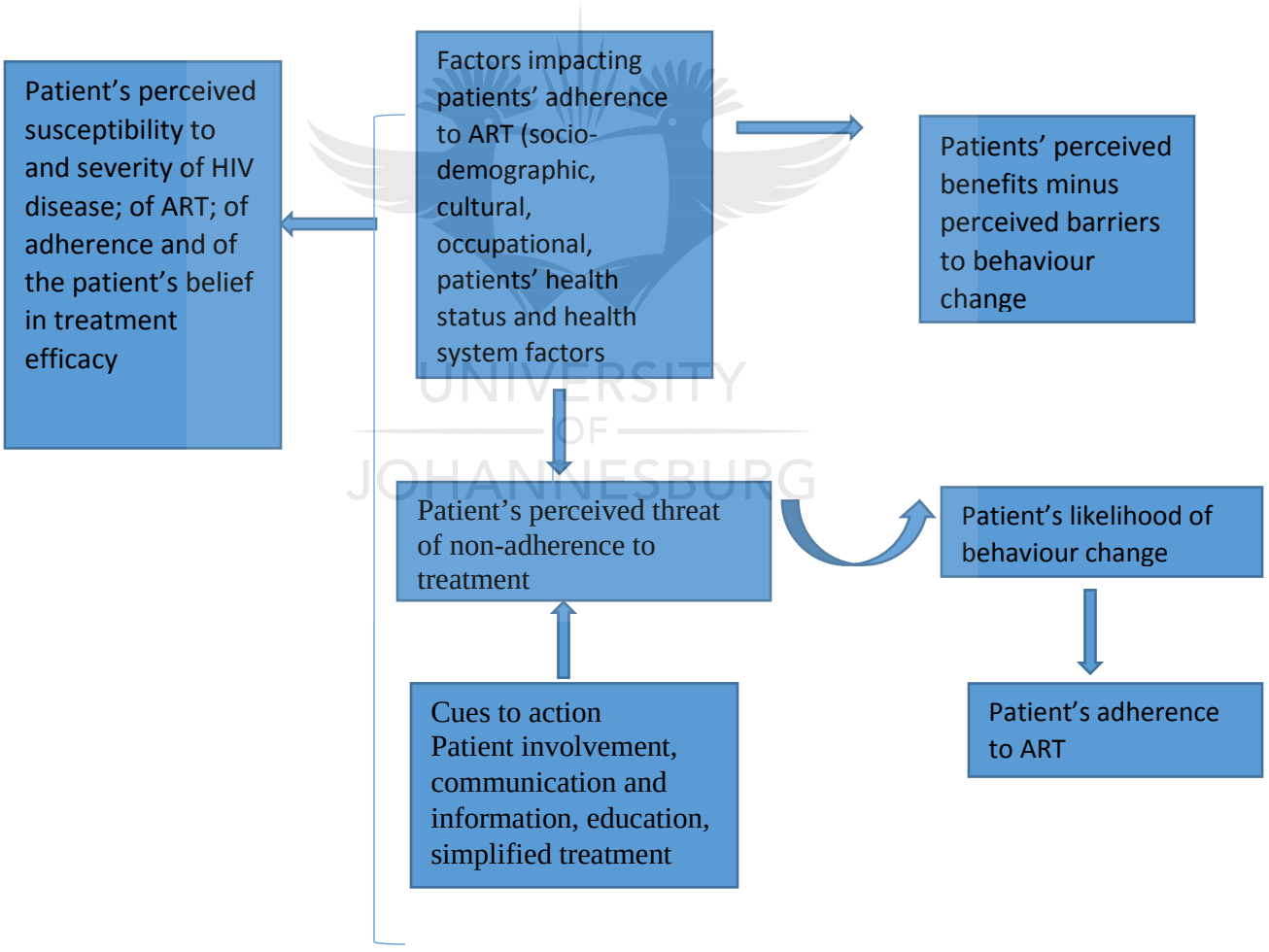

Figure 3: Study conceptual framework

2.2 Literature search strategy

For this study, the literature search strategy involved breaking the title of the study and identifying the key concepts to be used in the search engines such as PICO model, PubMed and Google Scholar. This model is used in medicine and health therefore since my title is health related PICO help to break it down into key terms and concepts. In this case the main concepts will be Antiretroviral therapy and treatment defaulting.

The search strategy for this study included use of the search engines such PubMed and Google scholar to search databases for relevant articles and journals. PubMed gives generic health and medical databases, offering reference to medical, nursing, and social care literature. Google scholar on the other hand gives a broader range of articles since it is multidisciplinary. The databases contain searchable organized collection of materials therefore are relatively easy to get the relevant materials from. Firstly, a list of keywords including the acronyms to prepare for search using either PubMed search engine was made. Then identified the type of literature of interest and the sources to search from, then established the scope for the search (Feresu,2019).

2.3 Literature review

The global incidence of HIV infection has stabilised and begun to decline in many countries with generalised epidemics. According to WHO (2011), the number of people receiving antiretroviral therapy continues to increase, with 6.65 million people getting treatment at the end of 2010. Recent published evidence from clinical trials has confirmed the powerful impact antiretroviral drugs have had on the epidemic as part of an effective package of options for HIV prevention. Sub-Saharan Africa has essentially the most severe HIV and AIDS epidemic in the world, although the burden of the epidemic continues to differ greatly between nations and regions. By 2015, 36.7 million people were reported to be living with HIV/AIDS globally, of which 25.6 million (69.8% globally) are from sub-Saharan Africa alone (Pepfar.gov., 2019).

Globally, Lesotho ranks second in HIV prevalence. Prevalence rates vary among Lesotho's 10 districts and range from 17.8% in Butha-buthe to 29.3% in Mohale's hoek, Berea's prevalence was reported as 23% (LePHIA, 2017). In June 2016, per the new Universal Test and Treat (UTT) guidelines released by the World Health Organization (WHO), Lesotho became the first African country to implement UTT guidelines. While these guidelines removed all restrictions to ART

initiation for HIV-affected people, actual ART coverage remained at 41% for adults and 40% for children.

It is well acknowledged that ART discontinuation hampers the progress towards achieving the UNAIDS treatment targets that aim to treat 90% of HIV diagnosed patients and achieve viral suppression for 90% of those on treatment (Unaids.org, 2018). Nevertheless, the magnitude, trend and risk factors for ART discontinuation have not been explored extensively. The contributing factors to defaulting ART were unclear with the defaulter rate of 28% in a study conducted in Ethiopia on defaulters from antiretroviral treatment in Jimma University Specialized Hospital, Southwest Ethiopia by Deribe (2018). This study aims to bridge the gap in knowledge and explore the possible factors associated with ART default in Lesotho.

2.3.1 Prevalence of defaulting ART

Kranzer et al. (2010), reported that globally defaulter rates vary from 32.7% in America, 12.1% in Europe to 39.4 - 79.4% in Africa. In Africa, this is mostly attributed to poor health systems. In a study conducted in Ethiopia on prevalence, trend and risk factors for antiretroviral therapy discontinuation among HIV-infected adults in 2003-2015, it was discovered that about 22.3% of patients enrolled had discontinued ART and most were females who were also co-infected with TB (Gesesew et al., 2017). According to Lesotho's 2015 UNAIDS Progress Report, the proportion of people who retained on ART after 12 months ranged between 70% and 80%. This means that about 20-30% of people defaulted ART.

2.3.2 Factors affecting default

According to Lesotho Ministry of Health, ART 2016 guidelines, a monthly visit should be scheduled for the patient following the two weeks check-up post ART initiation for medication refill and clinical evaluation until at six months when the patient will receive first viral load monitoring test (Lesotho MOH, 2016). If the viral load is below 1000 copies per mill-metre of blood, the patient is said to be virally supressed. The virally suppressed patient is eligible for multi-month dispensing until the next viral load after six months. Viral monitoring will then be done annually provided adherence to medication is good and there are no new opportunistic infections. The patient who does not adhere to the clinic appointment dates and miss appointment date for more than seven days is therefore categorised as a defaulter (Lesotho MOH, 2016). There are a

range of factors which can contribute to patient's defaulting to treatment which can include socio-economic factors, demographic factors, cultural practices, patient-related and facility-related factors. Musheke et al. (2012) stated that factors affecting the retention of patients in ART programmes can be categorized as: patient, social, health systems and economic related factors. The classification is not inclusive, and all these factors are interrelated rather than isolated.

2.3.3 Socio-demographic factors

The findings of a study on influence of gender on loss to follow-up in a large HIV treatment programme in western Kenya, shows rate of lost to follow-up of the study participants as 54% and the overall incidence of lost to follow up was 25.1 per 100 person-years. The factors associated with lost to follow-up were young age, long travel to the clinic, patient's disclosure of HIV status and gender were men were found to be at increased risk of ART defaulting (Ochieng-Ooko et al., 2018). In another study conducted in Nigeria, it was shown that there was a statistically significant association between adherence to ART and marital status, source of income, and occupation (Suleiman and Momo, 2018).

2.3.4 Economic and cultural factors

A study on default from Anti-Retroviral Treatment Programme in Sagamu, Nigeria by Daniel et al. (2010), found that 36% of the study population defaulted treatment and among the reasons for defaulting were; opting for alternative medicine, loss of interest in the programme and financial constraints. One of the major factors affecting access to healthcare include insufficient funds to travel to health centres, so people often run out of ARVs without being able to get more. The Lesotho Demographic and Health Survey 2014 found 38% of rural respondents had to walk for more than two hours to their nearest health facility compared to around 3% of urban respondents and those who came from poor economic backgrounds were most affected and had high defaulter rate.

Cultural factors (individual beliefs and perceptions) are notoriously complex concepts and shape people's identities and influence their attitude and behaviours. The individual behaviours and beliefs about health and seeking treatment can adversely affect healthcare utilization and adherence to medication. In a study conducted in Nepal, it was found that some cultural practices and cultural beliefs contribute to ART default. It was documented that some of the cultural

practices such as use of traditional medicines, visiting herbalist or using herbs and fasting interrupted ART intake (Wasti et al., 2012).

2.3.5 Facility and patient related factors

In Botswana, a study conducted on health-related quality of life of antiretroviral treatment defaulters, findings showed various factors contributing to defaulter including depression, lack of access to healthcare services, poor financial resources and medication side effects among others (Ndubuka et al., 2018). Both healthcare providers and patients identified medication side effects, staff shortage, medication stock-out, congested facilities, long waiting times, travel distance and cost of transportation as contributing to poor retention in care in one study conducted in Zambia by Mukumbang et al. (2017). This kind of information is vital in side effect assessment, management and prevention for successful ART retention. Other facility related factors that affect ART adherence were documented in a study conducted in Malawi by Chirambo et al.(2019), as poor relationship between health care workers and patients, shortage of ART trained health care workers and geographical accessibility of ARVs.

In another study conducted in Ethiopia, several facility related factors that impact ART adherence were documented. Results showed that negative experiences of receiving HIV care which were felt to adversely affect retention were both provider and system based. Negative health system factors included frequent change of clinicians, which may result in changed of treatment plans; a poor medical records system that might result in patient records being lost or incomplete; overcrowding and shortage of chairs in waiting rooms; and long waiting time for appointments, test results, or other services. For example, turnaround time for results from laboratory tests such as CD4 count was long, which means results are not immediately available, hence patients might have to return several days to a week after an initial visit for counselling about their results. (Lifson et al., 2012).

2.3.6 Social support related factors

Patients' social support and disclosure have also been linked with ART adherence. Patients with strong and stable social support who have also disclosed their HIV status are more likely to adhere to ART than those who lack emotional and social support and who have kept their HIV status a secret from people close to them. This is linked to the partners' HIV status as it has been documented that when the patient's partner knows his/her status, it becomes easy for them to

disclose and support each other especially if both are HIV positive. According to Asefa et al. (2013), compared to those whose partners were HIV positive, the risk of defaulting from ART treatments were 5.14 times higher among patients whose partners were HIV negative [AOR=5.1; 95% CI 1.59 to 16.63], and 2.83 times higher among patients whose partners HIV status were unknown or not tested [AOR=2.8; 95% CI 1.23 to 6.50]. A patient whose partner was HIV-negative or unknown HIV status was more likely to default from treatment. Similar findings have been reported by study done in Ethiopia by Deribe et al. (2018).

2.4 Summary and transition

Chapter two discussed the literature review conducted by the researcher with the focus on the overall aim of this study, which is to identify factors contributing to high defaulter rate of ART patients in Berea District, Lesotho. The chapter reviewed relevant literature from previous studies on factors associated with or contributing to ART defaulting. Several sources were consulted, including medical and research textbooks, the latest relevant journals, WHO publications, district reports, the internet and ministry of health publications and guidelines. Internet search engines used included PubMed and Google scholar.

CHAPTER THREE: METHODOLOGY

3.1 Study design

A quantitative case control study design was used for this project. Case control studies are relatively easy to implement and considering the time and budget constraints, this is the best suited design to address the research questions (Creswell, 2014).

3.2 The study sites

The study was conducted in two health facilities of Berea District, Lesotho. The facilities include Holy Family Health Center and Berea Hospital. In the west, Berea District shares a border with the Free State Province of South Africa. It shares its other borders with districts within Lesotho. Berea District has an area of 2,222 square kilo meters. It has a population of 262,616, which is 13% of the total country population. The population density is 113.00 persons per square kilometer, compared to 62 for the country. It is among the six districts with high prevalence of HIV. Currently HIV prevalence in Berea is 23% compared to 25.6% country prevalence (LePHIA, 2017). Berea is the closest district to the capital city of Lesotho, Maseru, and is among the five PEPFAR supported districts for HIV and AIDS. PERFAR is a United States governmental initiative to address the global HIV/AIDS epidemic and help save the lives of those suffering from the disease. Berea is also used as a model district in most of the Ministry of Health programmes including the HIV programme because of its accessibility and reduced complexity compared to the capital city which has a high population that need services. Additionally, most of the public health programmes are piloted in this district. Below, in Figure 4 is the map of Lesotho showing the location of Berea District and HIV prevalence per district (LePHIA, 2017). Figure 5 indicates the study sites.

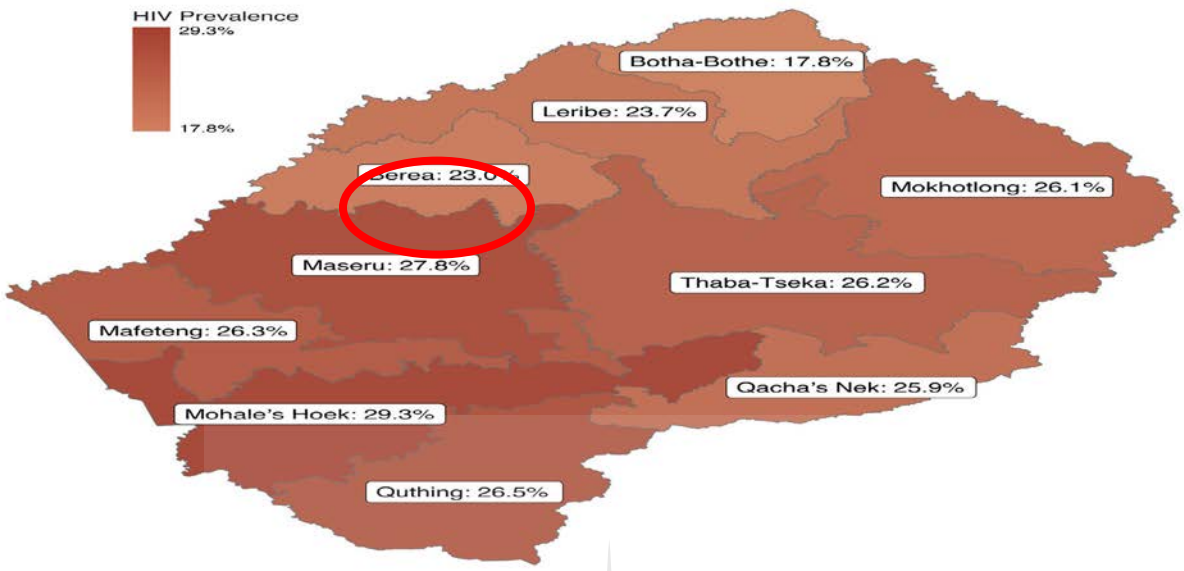

Figure 4 District HIV prevalence, LePHIA: 2017

Source: LePHIA 2017 report

Figure 5: A map of Berea showing the study sites
Source: Master facility list:2017

3.3 Target population

The target population for this study is HIV positive patients who are 18 years and above, registered in two Berea health facilities between January 2016 and December 2017 both males and females. These include patients who have a documentation of defaulting ART during the stipulated study period and they will be compared with the patients who are active or have no documentation of defaulting treatment in the same cohort.

3.4 Study population

The study population included all adult females and male, 18 years of age who are HIV positive and were initiated on ART at the two selected sites between January 2016 and December 2017 and who were regarded as defaulters to ART treatment according to the national ART guidelines. In this study, a defaulter is a patient who missed medical appointment and medication refill between seven days and 90 days. ART patients younger than 18 years of age or who had defaulted their ART for less than seven days or more than 90 days were excluded.

3.5 Sampling

Random sampling technique was used for sampling the study population. This allowed all potential participants to have an equal chance of been selected in the sample frame. Listing of all eligible patients was done from the register. All patients who defaulted were randomly selected from the defaulters list to make a sampling frame of 161 cases. Another sampling frame was made from all active patients listed without documentation of default in the same time frame, and 161 were randomly selected to participate. For every case of ART default identified in the period of study, 1 control was selected that followed the case in the register until the sample size of 322 cases and controls required for the study was reached as per the calculated sample. However, during data collection, the actual total sample ended up being 500 to compensate for some of the missing variables because of incomplete information and poor documentation. Sample sizes of 15 cases and 15 controls were selected in a similar manner to conduct the pilot study and validate the data collection tool (Keary et al., 2012).

3.6 Sample size estimation

The sample size was calculated using the Centers of Disease Control and Prevention (CDC) EPINFO program for a case-control study design.

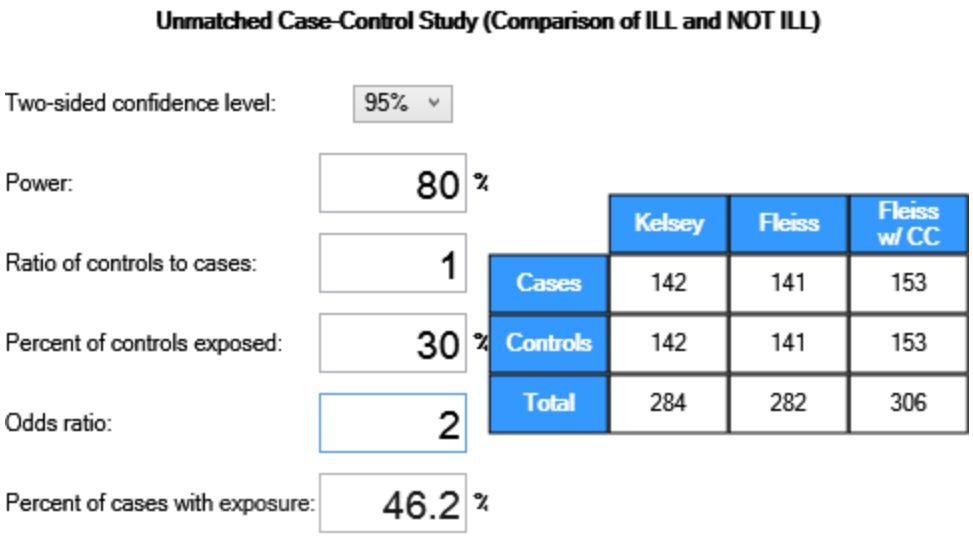

Figure 6: EPINFO 7.2 sample calculation
Source: (CDC) EPINFO

A sample size calculation indicated that 153 cases and 153 controls would be necessary for 80% power to detect an odds ratio of 2. This calculation assumed a two-sided test with confidence interval of 95%. The study used the EPINFO 7.2 to calculate and estimate the sample as shown in the Figure 6 above. The study had a sample of 153 cases and 153 controls based on a two-sided confidence level (1-alpha) of 95%, an 80% power to assess the prevalence of antiretroviral drugs defaulters, and a ratio of controls to cases of 1:1. Assuming that the traditional risk factors explain 5% of contingency for multiple comparisons and missing data, the total sample size for the study ended up being (153 + (8) =161 cases and 161controls to a total of 322. During data collection, the sample size was extended to a total of 500.

3.7 Inclusion Criteria

The inclusion criteria involved all adult females and males, 18 years of age who are HIV positive and were initiated on ART at the two selected health facilities between January 2016 and December 2017 and who were regarded as defaulters to ART treatment according to the national ART guidelines. In this study, a defaulter is a patient who missed medical appointment and medication refill between seven days and 90 days.

3.8 Exclusion criteria

ART patients younger than 18 years of age or who had defaulted their ART for less than seven days or more than 90 days were excluded. Another exclusion criterion was all patients who have transferred out of the facility or have a documented death as an outcome.

3.9 Data types

The data for this study was collected from existing records and no interviews were carried out. Most of the variables that were collected and analyzed were categorical and few continuous data from the age and CD4 count. The age of the participant at the time of ART registration forms part of a continuous data set; it starts from 18years up to 72 years as per the eligibility criteria. Another set of data that forms part of continuous data is the participants' CD4 count. This is a numerical value starting from as low as below 100 cells/mm up to above 1200 cells/mm (Azia et al., 2016)

Table 1: Study variables

Variable type	Variable name	Variable source	Level of Measurement
Dependent Variable	antiretroviral treatment defaulting	ART register and patient fie.	Categorical
Independent	Marital status	Patient file, data abstraction form.	Nominal
Independent	Gender	Patient file, data abstraction form.	Nominal
Independent	Employment status	Patient file	Dichotomous
Independent	Socio-economic status	Data abstraction form.	Ordinal
Independent	Patient's health status	Patient file	Dichotomous
Independent	Age	Patient file, data abstraction form.	Continuous
Independent	Partner's HIV status	Patient's file	Nominal
Independent	Treatment Supporter	Patient's file	Nominal
Independent	Opportunistic infections	Patient's file, ART register	Nominal

Independent	Side effects	Patient's file, ART register	Nominal
Independent	WHO Stage	Patient's file, ART register	Ordinal
Independent	CD4 count	Patient's file, ART register	Continuous

3.10 Sources of data

The sources of data for this project included medical records and registers used to collect data routinely for patients' registration, management, and follow-up. The data came from secondary data sources, ART register and ART care card, and was extracted using a pre-coded questionnaire in the form of data abstraction form. Data that was abstracted was patients' level data entered in the data sources by the clinicians routinely as they see and monitor patients on ART. These data covered the period of June 2016 to December 2017 for the selected patients who form part of the study population.

The main data source that was used to obtain information was the ART register found at the ART corners in the facilities used to register all HIV positive patients enrolled into HIV care and initiated on ART. Upon diagnosis with HIV, patients are registered in ART registers and initiated on treatment and all patients' biographic data, clinical staging, baseline, and follow-up tests are recorded. The second data source that was used is the ART care card. This is a tool that is used to monitor patients on ART for their monthly follow-up visits. Patients' biographic data, staging, cross functionality, adherence to medication and scheduled appointments are recorded routinely as they come for the clinic visits. These are all records which secondary data sources and raw data were collected using data abstraction form and analysed to answer the research questions. (Data abstraction form attached in the appendix 1).

3.11 Instrumentation

The questionnaire was used to extract data from the patients' medical records. The questionnaire was developed based on the research questions and all the variables that needed to be assessed were taken into consideration. The data collection tool consisted of five different sections. It was created in such a way that each of the five sections responds to the research question and covers the study variables. It has pre-coded responses to aid smooth data collection, minimise errors and simplify capture into the data base.

The first section, which is section A of the data collection tool addressed demographic information of the study participants. This section helps in collecting all the information needed to characterise study participants which is important to answer research question. Section B was designed to capture information on patients' social support. This information is important as it helps to assess whether having social support impact on ART adherence and what kind of social support seems to have more impact. The third section was on patients' health status. This section helps to examine state of health of patients at enrolment, to evaluate if patients' health status contributes to ART adherence or non-adherence. Section D collected information on patients' treatment history. It is important to know this information to decide if patient is a defaulter or not, and whether patient experienced any side effects or not which might impact on his/her adherence to ART. The last section was on drugs availability at the facility and days ART is offered as these could directly affect patients' adherence to ART. (See Appendix 1)

3.12 Data collection methods

The data collection was done from the secondary data sources; ART register and ART care card and was extracted using a pre-coded questionnaire in the form of data abstraction form. Data that was abstracted was patients' level data had been entered in the data sources by the clinicians routinely as they see and monitor patients on ART. These data covered the period of June 2016 to December 2017 for the selected eligible patients who formed part of the study population.

Document/records review was used for this project. Document review is a way of collecting data by reviewing existing documents. Data was abstracted from the existing patients' records such as ART register and HIV care cards. The data abstraction form had a heading and a unique participant's identification number. It was organized into five sections, and each section addressed a different variable. For instance, section A addressed patient's biographic data. For each variable, there was a question and the pre-coded answer options were provided.

3.13 Pilot study

The pilot study was conducted to check the validity and reliability of the data collection tool. Data was collected from one of Maseru facilities on Friday afternoon of the 17th January 2020 because of its accessibility to the researcher. The researcher reported to the facility manager and explained the nature of the exercise and requested access to patients' records, ART register and ART care card.

The cohort whose data was to be extracted was identified and patients' files which were going to be used pulled from the filing cabinets and put aside. A total of 10 records were reviewed for completeness and availability of data. They consisted of 6 patients who had no record of treatment interruption or default as the control and 4 patients who had a record of treatment interruptions or default during the stipulated study period. The data extraction tool was therefore not modified as it produced credible and consistent data.

3.14 Validity

Validity of data collection was checked with regards to content, criteria and face validity. Face validity was evaluated by checking the questionnaire against the data sources. The questionnaire seemed to be in agreement with the concept being tested and appeared to be a valid measure of the concept which is intended to be measured just on the face of it. The questionnaire was evaluated to what extent it measures or covers the construct of interest under study. It was evaluated as to what extent the data collected represented the variable they are intended to measure. The correlation between the findings on the selected subjects and the variables was checked to see if the criteria used to select the participants gave yield to the desired variables. The questionnaire was therefore considered valid as a data collection tool with a requirement to adjust the data collection technique to cater for questions that could not be addressed by data abstraction alone (Feresu.2019).

3.15 Reliability

Reliability of the data collection tool was assessed in terms of consistency, retest correlation and inter-rater reliability. The consistency of measure of the data collection tool on the same data sources in a different time period was assessed. The tool was also checked for consistency in interpretation of the questions to find out if the same data will be collected when used by different people using the same data sources. The same patients' files were used twice to abstract data and the two sets of questionnaires evaluated to check if the yielded the same responses from the data sources. The data collection tool was found to be reliable as it produced the same responses for the two sets of questionnaires abstracted at different times. The data collection tool repeatedly produced the same response regardless of when the data was abstracted. The data was found to be reproducible.

3.16 Data analysis

Statistical Package for the Social Sciences (SPSS) version 26 was used to examine the association and the relationships between socio-demographic, cultural, health related and patient related factors, that is the relationship between the dependent and the independent variables. The analysis was carried out by hypothesis as follows:

For objective 1: To assess the prevalence of defaulting for patients on ART in Berea District. The number of defaulters was counted for the specific time of study as the numerator. The prevalence was calculated for Berea District, then for the hospital and for the health facility for HIV patients. This means each entity population was the denominator.

For objective 2: To assess if there is a relationship between defaulting to ART for patients in Berea District and socio-demographic, occupational, patient related and health system factors.

Frequency distribution and cross tabulations were used to examine the relationship between defaulting to ART compared to no defaulters by socio-demographic factors such as age and sex, education, marital status, employment status. Bivariate and Multiple Chi-square tests, p-values, and 95% confidence intervals were used to establish if there were statistically significant associations between socio-demographic factors and adherence to ART adherence. The relationship between health system factors and ART defaulting was described. Comparisons were made between defaulters and no defaulters by health system factors such as availability of drugs or non-availability. Bivariate and Multiple logistic regression models were used to compare defaulters and not defaulters, in terms of dealing with health system factors. Chi-square test, p-values, and 95% confidence intervals were used to establish if there is a statistically significant relationship ART defaulting and health system factors.

Objective 3: To examine if there a relationship social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

Frequency distribution and cross tabulations were used to examine the relationship between defaulting to ART compared to no defaulters by social support, patients' health status and

treatment history. Bivariate and Multiple Chi-square tests, p-values, and 95% confidence intervals were used to establish if there were statistically significant associations between social support, patients' health status and treatment history and adherence to ART adherence. Comparisons were made between defaulters and no defaulters. Bivariate and Multiple logistic regression models were used to compare defaulters and not defaulters, in terms of social support, patients' health status and treatment history. Chi-square test, p-values, and 95% confidence intervals were used to establish if there is a statistically significant relationship ART defaulting and social support, patients' health status and treatment history

3.17 Ethical considerations

The research proposal was submitted to the University of Johannesburg, Faculty Academic Ethics Committee and Higher Degrees Committees (Appendix 3) for review and approval and to the local National Health Research Ethics Committee of Lesotho (Appendix 5).

3.17.1 Access to participants and document record

A written application to Lesotho Ministry of Health National Health Research Ethics Committee was made to obtain approval to conduct the study in Berea District at the two facilities selected and to obtain permission to review patients' documents and records in both facilities.

3.17.2 Obtaining informed consent

All data for the study were obtained from the patients' medical records. There was no need to involve or meet with the patients, therefore obtaining consent was not necessary. Application for a waiver of informed consent for secondary data use was done (see Appendix 2).

3.17.3 Right to anonymity, confidentiality, and privacy

The questionnaire was completed by extracting data on anonymous individuals. Each facility was given a project specific code to allow for responses and findings of the facility to be handled confidentially by the researcher. Such findings were not disclosed to facilities and/or to management singularly as the aim is not to expose facilities performance on ART retention. The study ensured that there were no personal identifiers used for all patients' documents abstracted. Unique study identification numbers were assigned to each patient's document.

3.17.4 Right to freedom of choice

All facilities managers were informed through a letter of the purpose of the study and that their facilities have been chosen to be part of the study. They were also requested to allow access to the information that would be collected during the research as aggregated reports and that study findings could be accessed through the management structure of the Lesotho Ministry of Health .

3.17.5 Right to community and community science

The facilities that participated in the study and other health related stakeholders may access any information pertaining to this research and the results of this research through the management of Lesotho Ministry of Health Research Coordinating Unit following the completion of the study. The existing quarterly research forum meetings whereby all the health stakeholders give research updates will be used to disseminate research findings. The findings will also be included in the Ministry of Health publications and during conferences targeted at disseminating new information to the public such as World AIDS day commemoration.

3.18 Timelines

The timeline for this study is as shown on the Gantt chart in Appendix 6. The research proposal development ran throughout the months of June and July 2019. The subsequent months were submission for ERC review, followed by data collection, capturing and cleaning, write-up, submission for examination and then publication in 2020.

3.19 Budget

The budget for this project is summarised in the table in Appendix 7. The student personally covered the costs of the study. The budget mainly consisted of travel expenses for data collection, printing, and communication. A consultant for data analysis was employed on to the project. To ensure safety and security of the study documents, a lockable cabinet was also sourced. A personal laptop was needed to carry out all the study activities from proposal writing, data collection and analysis, and writing of the dissertation.

CHAPTER FOUR: RESULTS

4.1 Introduction

The purpose of this study was to obtain an in-depth under-standing of the factors that contribute to treatment defaulting amongst HIV positive patients who are enrolled in the ART treatment programme in two health facilities of Berea District, Lesotho. The findings of this study could assist policymakers and authorities to develop innovative approaches to ensure treatment adherence and retention among HIV positive patients enrolled into care and treatment. Secondary data was used to answer the research questions. The sample size was 500. In this chapter, a report of the study findings is presented. The report for each research question is presented; the crude odds ratio (OR) and adjusted odds ratios (AOR) along with their confidence intervals (CI). The study had three research questions and the statistical findings in relation to each research question are presented, specifying which factors were statistically significant at 95% CI.

4.2 Data Analysis

An unmatched Case-Control Study designed to test the study hypotheses was adopted. Secondary data from the patients' medical records of 2016 to 2017 was used. The results of this study are based on the frequency distributions and the logistic regression analysis that were performed on the data. The calculated sample size required for this study was 322 (161 cases and 161 controls). However, the actual sample size obtained was 500 (267 cases and 233 controls) (Rooney.2018).

4.3 Results

4.3.1 Characteristics of HIV positive patients enrolled at two Berea District facilities who defaulted ART addressing research Question 1

RQ1.What is the prevalence of defaulting to antiretroviral treatment for patients in Berea district?

H01: The prevalence of defaulters for patients on ART at Berea district is not different from the general population in Lesotho

HA1: There is significantly high prevalence of defaulters for patients on ART at Berea district compared to the general population in Lesotho.

The number of defaulters was counted for the specific time of study as the numerator. The prevalence was calculated for Berea District, then for the hospital and for the health facility for HIV patients. This means each entity population was the denominator. ART default for Berea

district ranges between one-point-eight and two-point-seven percent (1.8-2.7%) in 2016 and 2017. Berea hospital ART default ranges between one-point-two and one-point-five percent (1.2-1.5%) while Holy Family was one-point-six to four-point-one percent (1.6-4.1%).

4.3.3.1 Descriptive statistics

The total sample size was 500. Cases constituted fifty-three-point four percent (53.4%) of the total sample size. Patients below 30 years contributed thirty-one percent (31%) of the total participants and they constituted forty-four-point nine percent (44.9%) of all the cases (defaulters) in the study. There were more female than male participants, accounting to sixty-five-point six percent (65.6%) of the study participants and contributed to fifty-four-point nine percent (54.9%) of the defaulters. A total of 248 (49.6%) of the study participants were married and contributed fifty-two-point one percent (52.1%) of the defaulters while widows only contributed 13.6%. More participants resided in the rural area constituting fifty-four-point four (54.4%) of the defaulters compared to those residing in urban and peri-urban area. Two hundred and fifty-four (254) patients were unemployed, which is more than half of the study participants, only twenty-six-point two percent (26.2%) were employed. Patients with primary education contributed most to the study participants and the cases in the study (42.3%),while those with no education were the lowest group with only eleven percent (11%). Table 2 below shows the ART default by socio-demographics for the patients enrolled into the study.

Table 2: Socio-demographic characteristics of HIV positive patient defaulters compared with non-defaulters at two health facilities in Berea District, Lesotho in 2016-2017

	Total		**Cases (ART Defaulters)**		**Controls (Non- defaulters)**	
Characteristics	**n**	**%**	**n**	**%**	**n**	**%**
Total	500	100%	267	53.4%	233	46.6%
Age						
< 30 years	155	31%	120	44.9%	35	15%
31 – 40 years	147	29.4%	50	18.7%	97	41.6%
41-50 years	111	22.2%	61	22.9%	50	21.5%
>50 years	87	17.4%	36	13.5%	51	21.9%
Sex						
Male	172	34.4%	87	32.6%	85	36.5%
Female	328	65.6%	180	67.4%	148	63.5%
Marital Status						
Single	112	22.4%	50	18.7%	62	26.6%
Widowed	68	13.6%	28	10.5%	40	17.2%
*Divorced	72	14.4%	50	18.7%	22	9.4%
Married	248	49.6%	139	52.1%	109	46.8%
Residential Place						
Rural	272	54.4%	147	55.1%	125	53.6%
Peri-Urban	160	32.0%	81	30.3%	79	33.9%
Urban	68	13.6%	39	14.6%	29	12.5%
Employment Status						
Unemployed	254	50.8%	101	37.8%	153	65.7%
Self-employed	115	23.0%	62	23.2%	53	22.7%
Employed	131	26.2%	104	39.0%	27	11.6%
Educational Status						
No Education	55	11.0%	20	7.5%	35	15.0%
Primary education	190	38.0%	113	42.3%	77	33.1%

Secondary education	167	33.4%	84	31.5%	83	35.6%
Tertiary education	88	17.6%	50	18.7%	38	16.3%

*Combined with other options such separated.

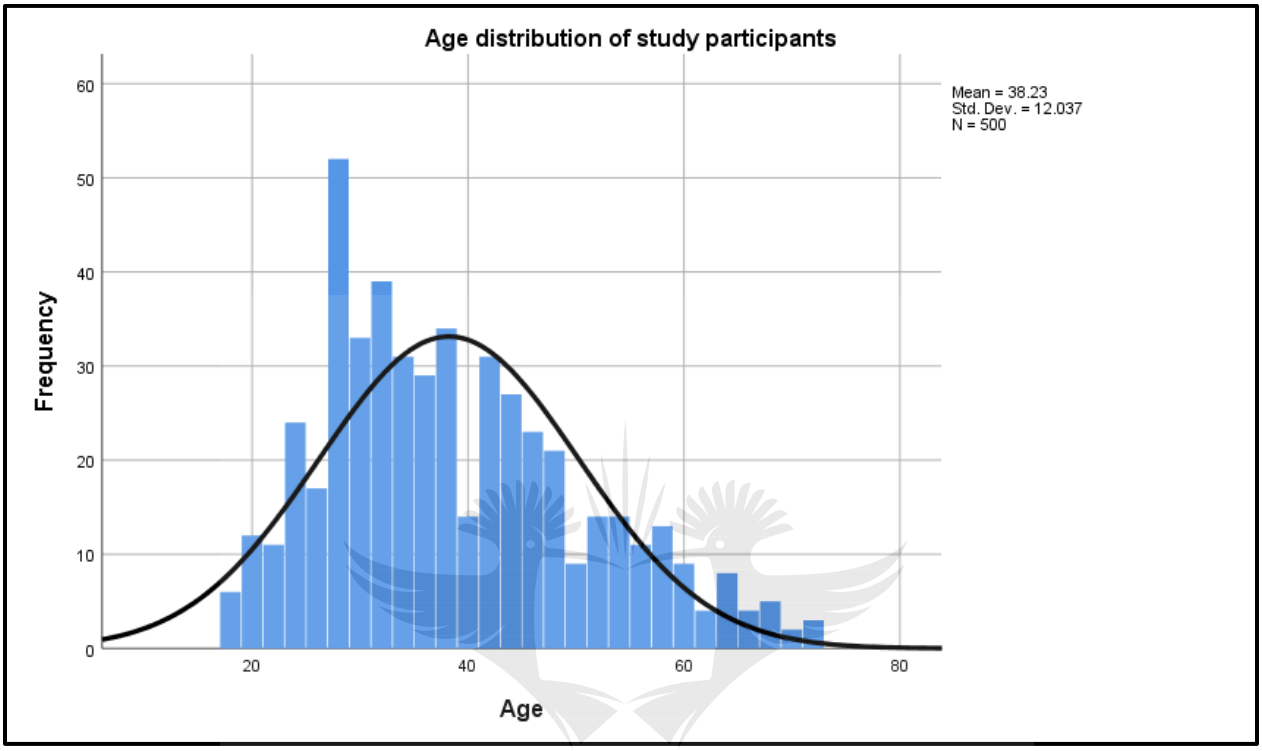

Figure 7: Age distribution of study participants

The age of the participants in the study represented by the histogram in Figure 7 above is normally distributed with mean age of 38.23 and standard deviation 12.037.

4.3.2 Crude odds and adjusted odds ratios of eligible HIV positive patients enrolled at two Berea facilities by socio-demographic characteristics addressing research Question 2

RQ2. Is there a relationship between socio-demographic, occupational, patient related and health system factors and defaulting to ART for patients in Berea District?

H02: There is no association between defaulting to ART for patients in Berea District and socio-demographic, occupational, patient related and health system factors.

HA2: There is an association between socio-demographic, occupational, patient related, health system factors and defaulting to ART for patients in Berea District.

Table 3 below shows the results of the crude odds ratios (OR) and the adjusted odds ratios (AOR) of the socio-demographic characteristics. Binary logistic regression was performed to calculate both the crude and adjusted odds ratios and their respective confidence intervals (CI). Firstly, the OR and CI were calculated comparing the cases and controls within each independent variable. After obtaining the crude odds ratios, possible confounding between the variables was controlled by computing adjusted odds ratios. There were specifically adjusted for age, sex, area of residency, educational status, marital status, and employment status in assessing the association between the socio-demographic factors and ART defaulting. All the six independent variables were included in the model comparing the cases and controls. Age group below 30 years was found to be less likely associated with ART default (crude odd ratio, 4.86; 95% cl, 2.75-8.58. Adjusted odds ratio, 0.45, 95% cl, 0.23-089; p= 0.021). Being widowed was found to be more likely associated with ART default (adjusted odds ratio, 2.81, 95% cl, 1.29-6.14 and p= 0.009). When looking at employment status of the patient, being unemployed was found to be more likely associated with ART default (adjusted odds ratio, 1.81, 95% cl 1.09-2.98 and p= 0.021). While self-employment was less likely associated with ART default (adjusted odds ratio, 0.21, 95% cl 0.10-0.42 and p<.001). Patients with primary education were found to be less likely to default ART (adjusted odd ratio, 0.34, 95% cl 0.16-0.72 and p=0.005). There were no statistically significant results in other socio-demographics.

Table 3: Crude odds and adjusted odds ratios of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea facilities 2016-2017 by socio-demographic characteristics

Characteristics	Crude Odds ratio	95% CI	*Adjusted Odds Ratio	95% CI	p-value***
Age					
< 30 years	**4.86**	**2.75-8.58**	**0.45**	**0.23-0.89**	**0.021**
31 – 40 years	0.73	0.42-1.26	0.87	0.46-1.64	0.656
41-50 years	1.73	0.98-3.05	0.83	0.44-1.58	0.568
>50 years	Reference	Reference	Reference	Reference	Reference
Sex					
Male	0.84	0.58-1.22	1.37	0.90-2.10	0.143
Female	Reference	Reference	Reference	Reference	Reference
Marital Status					
Single	**0.63**	**0.40-0.99**	1.70	0.85-3.42	0.136

Widowed	**0.55**	**0.32-0.95**	**2.81**	**1.29-6.14**	**0.009**
**Divorced	1.78	1.02-3.12	0.52	0.14-1.91	0.322
Married	Reference	Reference	Reference	Reference	Reference
Residential Place					
Rural	0.87	0.51-1.50	1.57	0.80-3.06	0.187
Peri-Urban	0.76	0.43-1.35	1.43	0.91-2.25	0.125
Urban	Reference	reference	Reference	Reference	Reference
Employment Status					
Unemployed	**0.17**	**0.11-0.28**	**1.81**	**1.09-2.98**	**0.021**
Self-employed	**0.30**	**0.17-0.53**	**0.21**	**0.10-0.42**	**0.000**
Employed	Reference	Reference	Reference	Reference	Reference
Educational Status					
No Education	**0.43**	**0.22-0.87**	0.67	0.27-1.69	0.400
Primary education	1.12	0.67-1.86	**0.34**	**0.16-0.72**	**0.005**
Secondary education	0.77	0.46-1.29	0.63	0.30-1.31	0.217
Tertiary education	Reference	Reference	Reference	Reference	Reference

*****Adjusted for age, marital status, residential place, employment status and educational status**.**

****** Combined with other options such as separated.

***P-value for adjusted odds ratio.

4.3.2: Social support, patients' health status and treatment history data of eligible HIV positive patient

3. To examine if there a relationship social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

H0: There is no association between social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

HA: There is an association between social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017.

Figure 8 below depicts the patient's adherence according to his/her marital status. ART adherence looks bad for patients who were single or married as compared to those who were widowed or divorced.

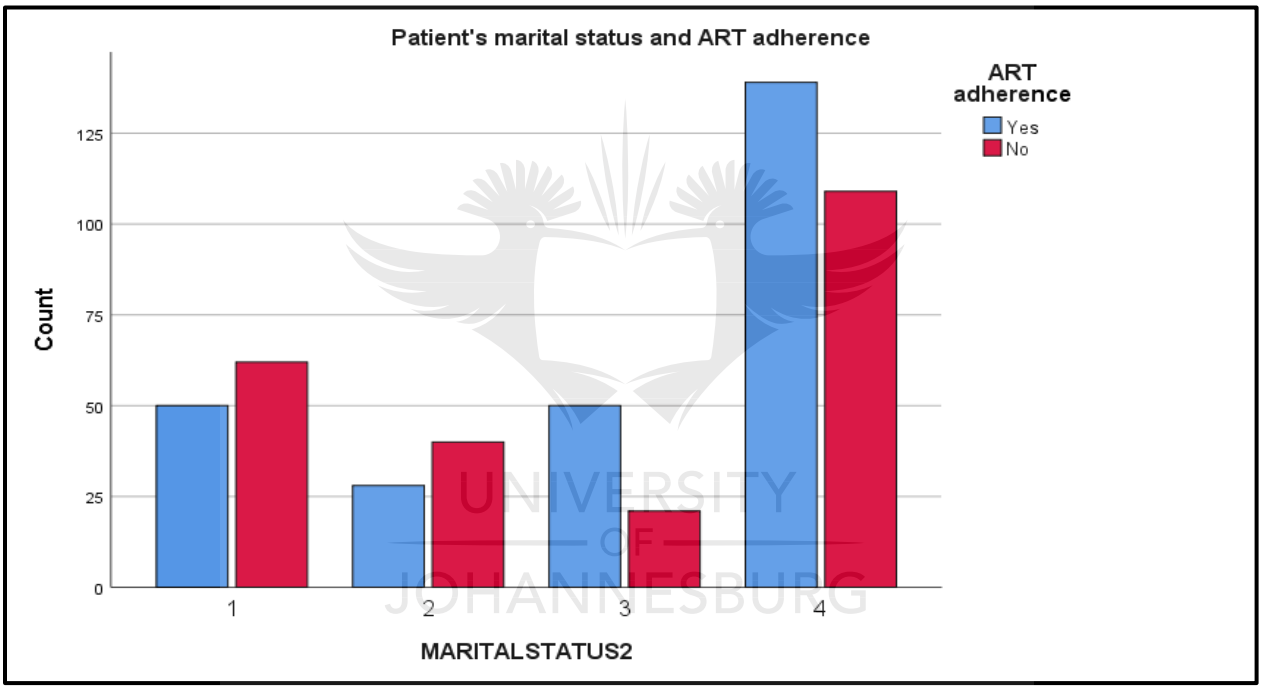

Figure 8: Patient's marital status and ART adherence
1= Married, 2= single, 3= Divorced/other, 4= Widow

In Table 4 below, the data shows patient's social support, health status and treatment history. Most of the patients had family members as their treatment supporters and account for forty seven percent (47%) of all the participants and those who were supported by their spouses or partners constitutes twenty one percent (21%) of cases (Figure 9).

Table 4: Social support, patients' health status and treatment history data of eligible HIV positive patient defaulters and non-defaulters enrolled at two Berea District health facilities 2016-2017

	Total		**Cases**		**Controls**	
Characteristics	**n**	**%**	**n**	**%**	**n**	**%**
Total	500	100%	267	53.4%	233	46.6%
Treatment Supporter						
Spouse	138	27.6%	56	21.0%	82	35.2%
*Friend	127	25.4%	81	30.3%	46	19.7%
Family member	235	47.0%	130	48.7%	105	45.1%
Partner's HIV status						
Positive	138	27.6%	63	23.6%	75	32.2%
Unknown/Unavailable	292	58.4%	166	62.2%	126	54.1%
negative	70	14.0%	38	14.2%	32	13.7%
WHO stage						
**Stage 3	62	12.4%	35	13.1%	27	11.6%
Stage 2	101	20.2%	59	22.1%	42	18.0%
Stage 1	337	67.4%	173	64.8%	164	70.4%
OIs screening						
Available	149	29.8%	84	31.5%	65	27.9%
Not Available	351	70.2%	183	68.5%	168	72.1%
CD4 Count						
<200	78	15.6%	46	17.2%	32	13.7%
200-500	341	68.2%	176	65.9%	165	70.8%
>500	81	16.2%	45	16.8%	36	15.5%
Side effects						
Yes	84	16.8%	56	21.0%	28	12.0%
No	416	83.2%	211	79.0%	205	88.0%
Drugs stock out						
Yes	145	29.0%	92	34.5%	53	22.7%
No	355	71.0%	175	65.5%	180	77.3%

* Combined with other option.

** Combined with stage 4

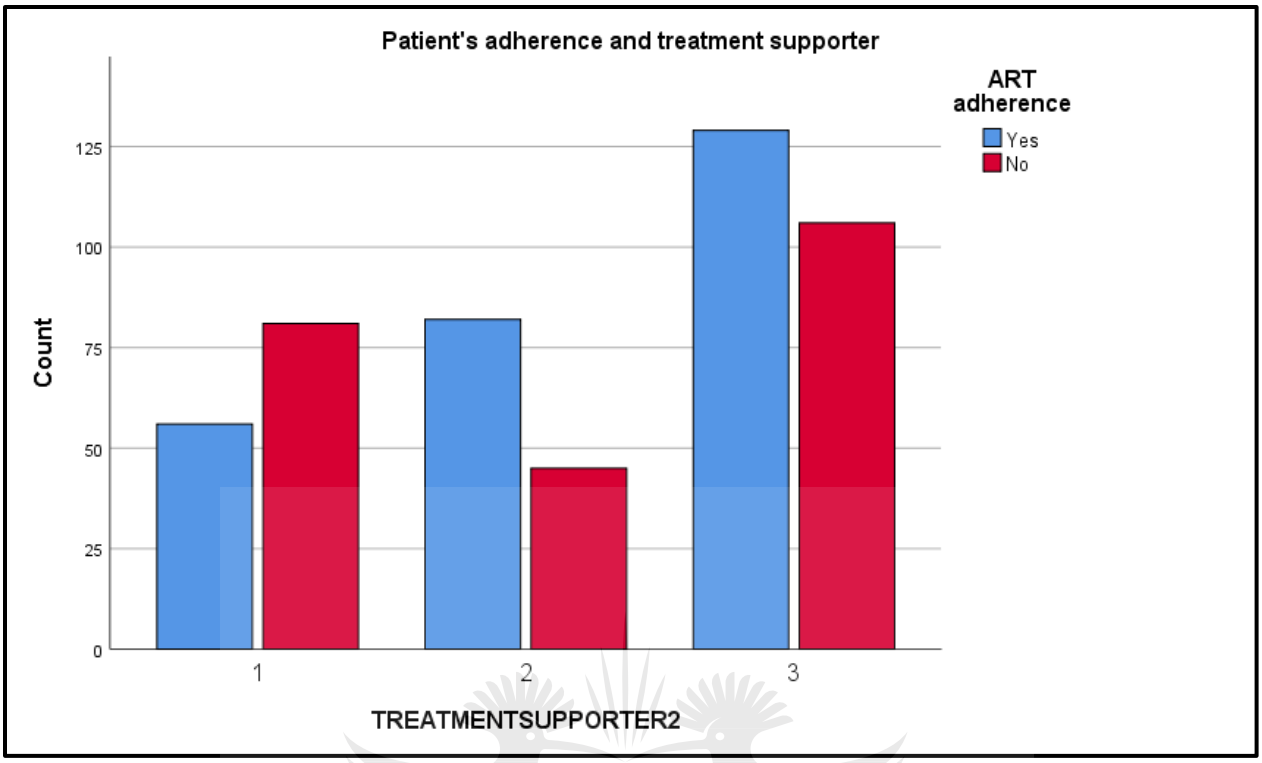

Figure 9: Patient's ART adherence and treatment supporter
1= spouse, 2= Friend/other and 3= Family,

When looking at patient's adherence from the perspective of their social support and their treatment supporter, most patients whose treatment supporters were their spouses or partners were less likely to adheres as compared to other categories of patients with a different treatment supporter such as family member or a friend.

Patients whose spouse' or partners' HIV status was unknown or unavailable contributed to more cases, sixty-two-point two percent (62.2%) followed by the positive status with twenty-four-point six percent (24.6%). See Figure 10 below.

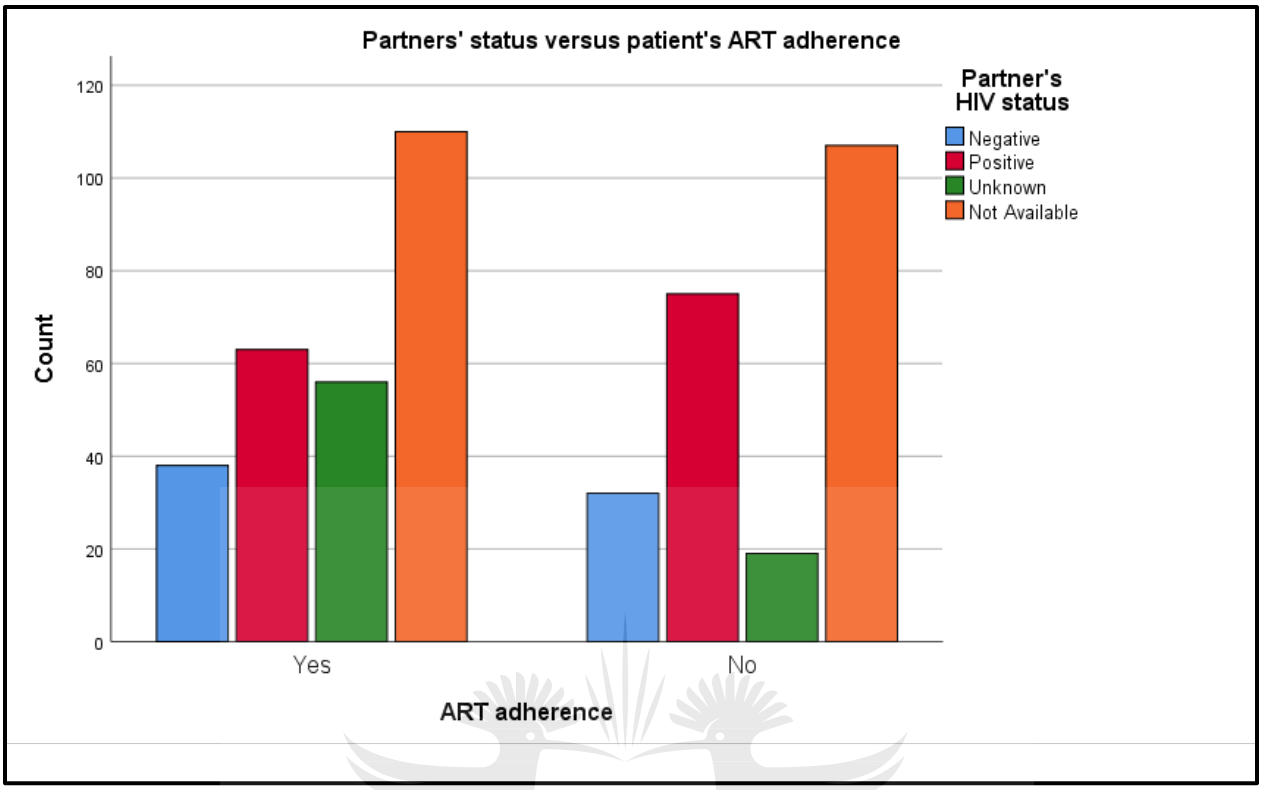

Figure 10: Partner's status versus patient's ART adherence

Figure 10 above shows patient's adherence is matched to the partner's or spouse's HIV status. Adherence looks good for patients with partners whose HIV statuses were either unknown or not available or documented.

Most of the patients (337), sixty-seven-point four percent (67.4% enrolled into the study were on WHO clinical stage 1,), while clinical stages 3 and 4 accounted for the lowest participants with only twelve-point four percent (12.4%). The WHO stages are measure of HIV/AIDS disease progression. The clinical events used to categorize HIV disease among infants, children, adolescents or adults living with HIV are divided into four stages for which a presumptive clinical diagnosis may be made (where syndromes or conditions can be diagnosed clinically or with basic ancillary investigations) and those requiring a definitive diagnosis (generally conditions described according to causation requiring more complex or sophisticated laboratory confirmation). WHO provides the clinical stage in simplified terms describing the spectrum of HIV related symptomatology, asymptomatic, mild symptoms, advanced symptoms, and severe symptoms. Fifty six percent (56.1%) of the cases had opportunistic infections present during screening while

forty-three-point nine percent (43.9%) of the controls had opportunistic infections (OIs). Sixty eight percent (68.0%) of the patients had CD4 count ranging between 200 and 500 cell/mm. Only fifteen-point six percent (15.6%) had very low CD4 count that was below 200cell/mm. Figure 11 shows the CD4 count distribution in the patients in the study.

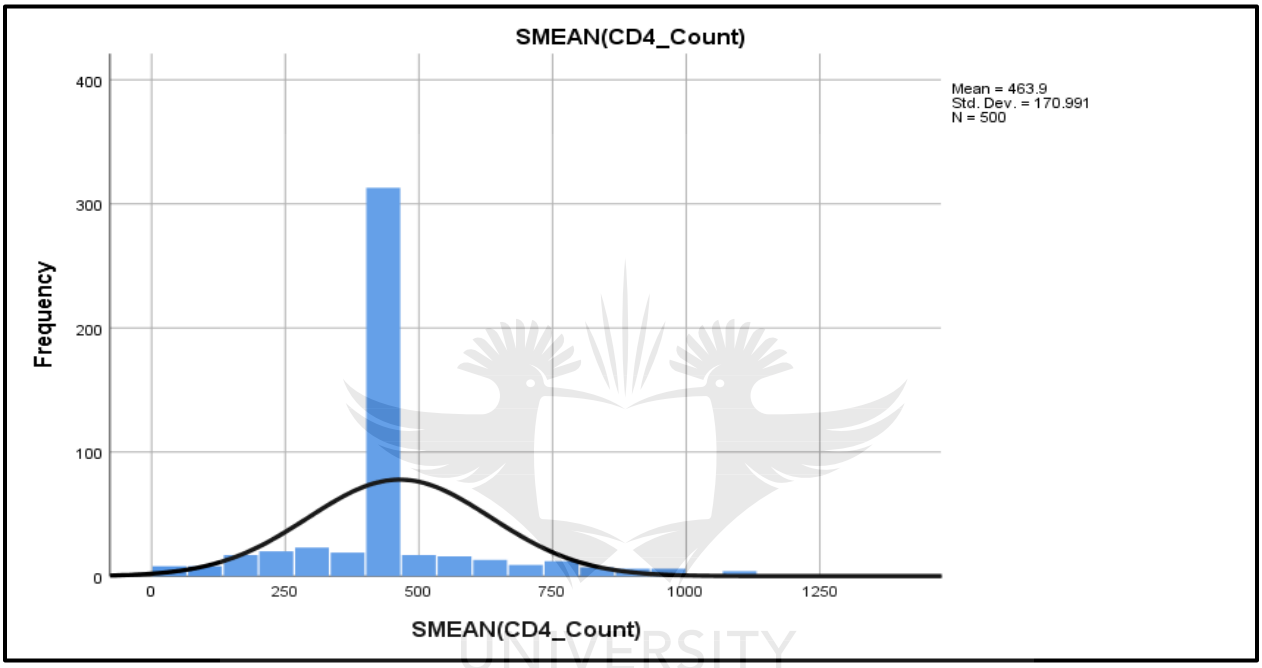

Figure 11: CD4 count distribution of the study participants

Figure 11 above shows the CD4 count distribution of all patients enrolled into the study. The CD4 is normally distributed with most of the patients having CD4 count around the 460 cell/mm which causes an outlier. The mean CD4 count is 463.9 and standard deviation is 170.991.

Table 5 below shows the crude odds ratio and adjusted odds ratio for patients' social support, health status and treatment history, and no statistically significant results noted after controlling for potential confounding factors except for drug stock outs, which shows that there is less likelihood of ART default associated with drug stock outs, (adjusted odds ratio, 0.61, 95% cl 0.40-0.94 and p= 0.023).

Table 5: Social support, patients' health status and treatment history Crude Odds and adjusted odds ratios

Characteristics	Crude Odds ratio	95% CI	*Adjusted Odds Ratio	95% CI	p-value****
Treatment Supporter					
Spouse	**0.56**	**0.36-0.86**	**1.64**	**0.99-2.70**	0.053
**Friend	1.42	0.91-2.22	0.78	0.47-1.29	0.339
Family member	Reference	Reference	Reference	Reference	Reference
Partner's HIV status					
Positive	0.71	0.40-1.26	1.17	0.64-2.15	0.610
***Unknown	1.11	0.66-1.87	1.27	0.71-2.26	0.415
negative	Reference	Reference	Reference	Reference	Reference
WHO stage					
****Stage 3	1.23	0.71-2.12	1.08	0.14-8.42	0.941
Stage 2	1.33	0.85-2.09	0.94	0.58-1.55	0.821
Stage 1	Reference	Reference	Reference	Reference	Reference
OIs screening					
Available	1.17	0.80-1.73	1.05	0.65-1.68	0.845
Not Available	Reference	Reference	Reference	Reference	Reference
CD4 Count					
<200	1.18	0.63-2.21	0.88	0.40-1.91	0.876
200-500	0.87	0.54-1.42	1.23	0.74-2.04	1.23
>500	Reference	Refence	Reference	Reference	Reference
Side effects					
Yes	**1.94**	**1.19-3.18**	0.73	0.42-1.26	0.252
No	Reference	Reference	Reference	Reference	Reference
Drugs stock out					
Yes	**1.79**	**1.20-2.66**	**0.61**	**0.40-0.94**	**0.023**
No	Reference	Reference	Reference	Reference	Reference

* Adjusted for age, marital status, residential place, employment status and educational status.
**Combined with other option.

*** Combined with not available.

**** Combined with stage 4.

***P-value for adjusted odds ratio.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The purpose of this study was to obtain an in-depth understanding of the factors that contribute to treatment defaulting amongst HIV positive patients who are enrolled in the ART treatment programme in two health facilities of Berea District, Lesotho. This evaluation has revealed strengths and weaknesses in the Lesotho ART programme. The completeness and accuracy of data, as demonstrated in facilities registers and patients' files, is insufficient to gauge a true picture of burden of ART default in the health facilities. This assessment serves to enlighten policymakers on the treatment challenges of ART patients. Factors influencing ART adherence among the study population according the findings were: patient's age, educational status, marital status, treatment supporter, side effects and drug stock outs. Sex, residential area, patient's health status such as clinical stage and CD4 count were not found to significantly influence adherence to ART. These factors can be addressed as interventions that mitigate illness cost-effectively needing no extra resources, hence are optimal to ART adherence and retention into care.

. Secondary data was used to answer the research questions. These data are not routinely analysed to assess the defaulter rate because of lack of resources therefore the country's ART programme is uniformed of the intensity of ART default. To address this gap, an unmatched case-control study was conducted to determine the prevalence of ART default and establish if there is any association between ART default and socio-demographic factors. De-identified secondary data from the facilities registers and patients' files were collected. The sample size for this study was 500 with 53.6% of these being HIV positive cases. In the analysis, the independent factors were categorized into two themes:

5.1.1 Prevalence of ART defaulters of patients enrolled at two facilities in Berea District, Lesotho in 2016-2017

The prevalence of ART defaulter was found to be fifty-three-point four percent (53.4%) which is higher than was expected because of the nature of the study; a case-control and the sampling procedure. Even though the prevalence seems quite high, it is in line with previous studies where as much as 40% prevalence of ART default was documented by Fox and Rosen, (2010) in a systemic review on patient retention in antiretroviral therapy programs up to three years on treatment in sub-Saharan Africa.

This is also consistent with other case-control studies where the prevalence of ART default becomes higher than the general population. For instance, Tesfaye et al. (2013) conducted a case-control study in Ethiopia on determinants of defaulting from antiretroviral treatment and found the prevalence to be fifty percent (50%) of the study population. However, other studies which were not case control have documented ART defaulter prevalence which is lower than this. A study by Gesesew et al. (2017) found that in every five people enrolled on ART, one becomes a defaulter, that is twenty percent (20%).

In another study by Chalker et al. (2008) on Monitoring Adherence and Defaulting for Antiretroviral Therapy in Five East African Countries, it was documented that prevalence of ART default ranges between ten percent (10%) and twenty-six percent (26%) and the findings were representative of the general population. Even though the results of this study do not represent the general population, it is evident that ART defaulter is a problem which requires an urgent public health response strategy.

5.1.2 Socio-demographic characteristics of HIV positive patient defaulters compared with non-defaulters enrolled at two facilities in Berea District, Lesotho in 2016-2017

The socio-demographic factors which were assessed include age, sex, marital status, educational status, residential area, and employment status. ART default is not well documented in Lesotho or possible factors that contribute to it though in national annual reports it is usually stated that ART retention is below expected target. The literature review of this study revealed that multiple factors are possibly associated with ART default. Those factors are discussed here within the context of the study.

The assessment of the association between socio-demographic factors and ART default; age, marital status, educational status, and employment status were all statistically significantly associated with ART default. Younger patients, 18 – 30 years, were surprisingly less likely to default ART compared to those in the older age group of above 50 years (AOR: 0.45; 0.23-089). We anticipated that the older age group would show more adherence to ART and default less since they are more stable and responsible as compared to the younger age group. These results also contradict other studies done in other countries, for example Hinkin et al. (2004) used MEMS to study the effect of patient age on medication adherence in 148 HIV-infected patients in the United States. They found mean adherence rate for the entire cohort to be 80.7%, with older patients (≥

50 years) showing significantly better medication adherence than younger patients (87.5% versus 78.3%). A possible reason for this difference with other studies could be that this age group of 18-30 contributed most to the sample more than other age groups making 49% of all the cases in the sample. It could also be that in Africa where life expectancy is low, for example Lesotho's life expectancy was 52.44 years in 2017, so people over 50 years of age already expect to die soon so do not follow-up on ART medication, while the younger ages of 18 to 30 years still expect a long life ahead and hence adhere to ART treatment (worldbank.2020). It has been documented by Ssebutinde et al., (2018) that older age patients are more likely to default ART treatment because of other co-morbidities such as arthritis, diabetes and hypertension which can lead to pill burden and treatment fatigue. Older age at ART initiation (> = 50 years) was associated with a higher risk of mortality with adjusted relative risk (RR) at 1.63, (95% CI 1.26–2.11) compared to younger age.

Patients with primary education or no education were also found less likely to default ART compared to those with tertiary education (AOR: 0.34, 95% Cl: 0.16-0.72). This seems to agree with other previous studies done. In a study conducted in Botswana by Weiser et al. (2003), the odds ratio of adherence for patients who did not complete secondary school as compared with those with higher levels of education was 3.87 (P = 0.02) showing that lower levels of education were associated with higher adherence. It was found that people with lower education are more likely to listen and follow the instructions they got from the health facilities and they have trust in health care workers.

With regards to marital status, the results showed that women who were widowed are more likely to default ART compared to those who were married (AOR: 2.81; 95% Cl: 1.29-6.14). There was no association established between place of residence, sex of the patient and ART default. This is consistent with the previous findings from Byakika-Tusiime et al. (2005) at three treatment centres in Kampala, Uganda who documented that marital status was associated with non-adherence (OR = 2.93, 95% CI 1.32–6.50) with married people more likely to adhere to ART as these group of people are more likely to be in stable relationships and have social support they need in their treatment journey.

5.1.3 Social support, patient's health status and treatment history of eligible HIV positive patients enrolled at two Berea facilities 2016-2017

Patients' social support, health status and treatment history were also assessed, and these included the following covariates: treatment supporter, partner's HIV status, WHO clinical staging, CD4 count, opportunistic infection screening, side effects and drug stock outs.

Results showed that patients who had their spouses or partners as their treatment supporter were less likely to default ART as compared to those whose treatment supporters were their family members or friends (OR: 0.56; 95% Cl: 0.36-0.86). Patients whose spouses or partners are treatment supporters adhere to treatment well as there are disclosure issues hence, they don't have to hide their status from their partners, hide their clinic visits or taking drugs. This is consistent with other studies, for example, in a study conducted by Tesfaye et al. (2013), it was documented that ART adherence is better for patients whose treatment supporters are their spouses especially if the spouse HIV status is positive rather than unknown or not tested.

Presence of side effects was statistically significant at 95% Cl, patients who experienced side effects during their treatment were more likely to default ART than those who did not have any documented drug side effects (OR: 1.94; 95% Cl:1.19-3.18). Side effects create a barrier to ART adherence for fear of getting even more sick from the treatment. These findings are consistent with the study assessing adherence to ART medication by patients living in an impoverished community in South Bronx, New York, USA where Weidle et al. (1999) found 14% of the study population defaulted on ART due to side effects.

Documented stock outs of drugs were also found to be more likely to contribute to ART default as compared to no drugs stock out (OR:1.79; 95% Cl:1.20-2.66). When facilities are running low on drugs supply, patients may be given one month supply of ARV drugs when a three months' supply had been prescribed especially for stable patients who have been on ART for a long time and it will mean unnecessary frequent visits to the ART centers and may discourage patients who travel long distances to the facilities. The study conducted in Zambia by Mukumbang et al. (2017) showed that ART clinics which ran low on the ARV stocks, affects the supply of medication received by the patients hence patients got discouraged to go to the health facilities only to come back without their drugs or with less than they normally get.

There was no statistically significant link between partner's HIV status, WHO clinical stage of the patient, CD4 count or opportunistic infections availability and the ART default. For these variables, there were issues of missing information that could not be found from the patients' records, for instance, either there was no record or test not done such as stock out of reagents for CD4 count hence lack of statistical significance as the data was not adequate to do the comparisons.

5.2 HBM application on study findings

The Health Belief Model (HBM) offers a potential explanation for adherence to ART and was explored in other studies. The HBM aims at assessing health behaviour of individuals through the perceptions and attitudes a person may have towards disease and negative outcomes of certain actions. When conceptualized in the context to chronic medication adherence such as ART, the HBM translates to the desire to achieve a better quality of life and the belief that adherence to ART will improve the health of the patient and this would influence whether a patient adheres to their medication or not. The HBM was conceptualized around the individual's beliefs and attitudes captured in four constructs representing the perceived threat and benefits. From the findings, perceived social support, perceived threat from side effects and perceived benefits all contributed to patients' adherence.

According to Janz and Becker (2010), HBM usefully describes demographic and psychological factors that influence health motivation, and more interestingly identifies the factors that perpetuate actual adherence behaviour. Therefore, patients who perceived themselves being at risk of developing serious HIV-related illnesses and who considered ART efficacy adhered to treatment than those who concentrated on the negative outcomes such as side effects.

5.3 Implications for Public Health

The findings of this study carry important opportunities for patients' clinical management. They provide insightful information about the possible factors contributing to ART default. This information can be used to inform the development of targeted interventions for HIV positive patients to reduce ART default and improve quality of life of the patients. At the individual level, getting rid of these barriers to ART adherence will help patients to be virally suppressed, which means less risk of new HIV transmission to the negative partners moving the country closer to achieving epidemic control. If patients' immunity is stronger with improved CD4 count, the risk

of opportunistic infections such as Tuberculosis which is still a major concern in Lesotho will be reduced.

It is important to note that from the findings, more than fifty percent (50%) of the study participants had no information about their partners HIV status, it was either left blank or status documented as unknown. This is of great concern as it shows that partner notification and index testing is still very weak in the HIV programme which pose a great challenge as patients who are already enrolled into the programme run a risk of HIV re-infection from the partner whose status is unknown and might be positive but not on treatment hence virally not suppressed presenting high risk of HIV transmission. Findings of this study also demonstrated that treatment supporters play an important role to ensure patients remain adherent to treatment especially where such supporters are spouses or partners. Therefore, it is important for the programme to re-enforce partner testing and strengthen indexing partners of HIV positive patients as they can support each other and to ensure that both individuals are on treatment to avoid re-infection.

Furthermore, identifying mitigating barriers of ART adherence could help the country's treatment programme and reduce ART re-initiation after default which carries the risk of resistance and bringing in of more expensive and toxic regimen in the picture which are difficult to manage. This would save the Lesotho HIV treatment programme money being used to buy second line regimens that could be invested in buying more drugs to treat side effects. The results of this study could also be used to modify health care policy and guidelines with regards to HIV care and treatment. As a result, patient-centred health care services and interventions to prevent ART default and improve the health of people living with HIV and AIDS who are on ART would be implemented to address the needs of patients regarding adherence issues. The study has the potential of helping the managers to improve service delivery and building the capacity of health care personnel. The results of this study can edge advocacy for good clinical practices and quality service delivery.

5.4 Limitations

It is not easy to access data from health facilities in Lesotho therefore making this the first limitation. During the process of abstracting data from patients' records a problem mainly due to incomplete records and missing information in the patient's files was discovered. Hence, making lack of available and/or reliable data one of the biggest limitations. The study was done retrospectively, therefore, retrieving all patients' files who had been initiated on ART two years

earlier a challenge due to the inconstant filing system used in the facilities. Lastly, because the study was done in two facilities only, the sample might not be representative of the general population hence the results cannot be generalized to the broader Lesotho population.

5.5 Strengths of the research project

The major strength of the study is the ability to include a wide range of patients registered in the same treatment cohort. The study compared both patients who were active and those who had defaulted, giving us a chance to have a better understanding of patients' dynamics when it comes to ART defaulting. The study builds on prior studies done in this field in other counties, giving a better chance of exploring areas with unanswered questions. Another strength was use of readily available data which did not require much resources and time for collection.

5.6 Conclusions

This evaluation has revealed factors associated with ART default for patients enrolled into care and initiated on ART. The findings of this study could assist policymakers and authorities to develop innovative approaches to ensure treatment adherence and retention among HIV positive patients enrolled into care and treatment. Some findings were surprisingly inconsistent with the existing body of knowledge. For instance, the study revealed that younger age group are more likely to adhere to treatment than older age. This requires more assessment to evaluate further the impact of age on treatment and other possible cofounders such as pre-existing health conditions and comorbidities in older age. It is important to note that spousal support is one of the factors that was found to be directly linked to ART adherence. Encouraging couple testing and disclosure of HIV status can positively contribute to treatment adherence therefore health care workers should pay more attention to patient's treatment supporter especially for married couples or patients with long term relationship and encourage their involvement in their partner's treatment journey for better treatment outcomes. The factors that were identified as associated with ART default can be easily mitigated as they do not need extra resources. Health care workers have to implement client-centred approach and create an enabling environment for patients to make decisions based on their treatment needs and lifestyle.

5.7 Recommendations

Assessing determinants of ART default is important to develop appropriate intervention programmes for specific populations. This study provides information on factors associated with

ART default and the findings established which factors are possibly influencing ART default. These findings can help inform programme interventions and activities at the facility level.

The first recommendation is for the health care workers to give particular attention to patient's socio-demographic characteristics at the time of ART initiation so that those prone to ART non-adherence such as the divorced, single or those in unstable relationships could be guided and assisted on best interventions possible to help them adhere to their medication. It is also recommended that the patient be advised and assisted to choose the treatment supporter who can help them through their treatment journey such as their partners or spouses so that it will be easy for them to take their drugs and attend medical follow-up without having to be secretive.

Thirdly, health care workers should pay attention to patients' medical history and assess for the presence of side effects so that they can counsel, treat and re-assure patients as oversight of these issues could hinder a patient's treatment adherence for fear of getting sicker from the drug side effects. Lastly, it is recommended that drug supply chain management be made a top priority from the national, district and facility level. Non-availability or stock out of drugs can negatively impact on patient's adherence as it can discourage them from going for their medical follow-ups and refills knowing they might make unfulfilled efforts to get their required drugs. Therefore, policymakers and the Ministry of Health, Lesotho should make sure there is always an adequate and reliable budget for supply of the HIV drugs. The ordering and stock maintenance should be diligently monitored, from ordering by the facilities up to the supply to patients by the ART national programme.

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Appendices
Appendix 1: Data abstraction form (questionnaire)

DATA ABSTACTION FORM STUDY IDENTIFICATION NUMBER----------

This form is to be filled for HIV eligible patients enrolled at the study site from January 2016 to December 2017 who are above 18 years.

Section A: ART patient demographic information

A1. Date of ART initiation

dd-mm-yyyy _____

A2. Patient's age at registration in years.

Age at registration---_____

A3. Patient's sex

Male _____1

Female _____ 2

A4. Marital status

Married _____ 1

Single _____ 2

Divorced _____3

Widowed _____4

Other _____ 5

A5. Patients Residential area

Urban _____ 1

Peri-urban _____ 2

Rural _____ 3

A6. Patient's employment status

Unemployed _____-1

Employed _____2

Self-employed _____3

A8. Patients educational status

No Education _____- 1

Primary education _____ 2

Secondary education _____3

Tertiary education _____4

Section B: Social support

B1. Patient's treatment supporter

Spouse _____1

Friend _____ 2

Family member _____3

Other _____4

B2. Spouse/partner's HIV status

Negative _____1

Positive _____ 2

Unknown _____3

Not available _____4

Section C: Patient's health status during enrolment

C1. WHO clinical staging

Stage 1 _____ 1

Stage 2 _____ 2

Stage 3 _____ 3

Stage 4_____ 4

C2. CD4 count

Write CD4 count in cells per mill- metre_____

C3. Function

Work _____ 1

Ambulatory_____ 2

Bedridden_____ 3

C4. Opportunistic infections screening

OIs available, _____-1

No OI _____2

Section D: Patient's treatment history

D1. Did patient interrupt/default treatment between 2016 and 2017?

Yes _____1

No _____ 2

D2. What is the duration of treatment interruption/default?

More than 7 days, less than 60 days _____1

More than 60 days, less than 90 days_____2

Not applicable _____ 3

D3. Did the patient experience any side effects during treatment?

Yes, _____1

No _____ 2

Section E: Drugs availability and services accessibility

E1. Is there a documented stock out of drugs during the study period?

Yes_____1

No _____ 2

E2. Which days does the facility offer ART services?

Every day _____1

Specific days of the week _____2

Other _____3

Section F: General Comments:

Appendix 2: Informed Consent Waiver Secondary Data (REC 15.0)

FACULTY OF HEALTH SCIENCES
RESEARCH ETHICS COMMITTEE

APPLICATION FOR A WAIVER OF INFORMED CONSENT:
SECONDARY DATA USE
(REC 15.0)

1. Instructions

1.1. This application form must be completed for all research proposals where the researcher(s) intend requesting access to secondary data and where, in the opinion of the researcher(s), it is not possible to obtain informed consent from patients or others to whom the data belongs.
1.2. In cases such as 1.1 a waiver of informed consent to access the secondary data should be applied for by completing this form and responding to conditions 1-6 below.
1.3. Completion of this form does not replace an adequate explanation of the relevant details of such a waiver request in the research proposal.

2. Details

Student Name	Limakatso Lebelo	Student Number	218100043
Supervisor Name	Prof S Feresu	Co-Supervisor Name	
Department	Public Health		
Research Title	FACTORS CONTRIBUTING TO HIGH DEFAULTERS FOR PATIENTS ON ANTIRETROVIRAL DRUGS IN BEREA DISTRICT; LESOTHO		
Date Submitted	16/09/2019	Version	1.0

3. Application

Condition 1: Was it foreseen that the data might be used for research (was the intention of creating the database/records for research purposes or for other purposes)?
Answer yes or no, and give details about the secondary data and the purpose for which it was collected.
No, the data collected is patient's medical information and the purpose of collecting data is for general patient management and program monitoring by the Lesotho ministry of health.

Condition 2: Are the data to be used de-identified or could they be de-identified?

Answer yes or no, and give details of identifiers present in the data and how these could be removed.
No, the data is not de-identified, but it could be de-identified. Currently on the records, the patient's details are there including names, addresses and the contacts number but for the study purposes no patient identifying information will be collected and study identification number will be assigned to distinguish the records.

Condition 3: Is there no more than minimal risk of harm from the research (if the waiver is approved)?
Answer yes or no, and explain the level of risk anticipated if the waiver is approved and the data used as intended.
Yes, there is no more than minimal risk of harm, the only risk is the invasion of privacy as personal medical records of the patients will be used.

Condition 4: Are the participant's rights and welfare unlikely to be affected (if the waiver is approved)?
Answer yes or no, and explain the anticipated effects on participant's welfare if the waiver is approved and the data used as intended.
Yes, the participants rights and welfare are unlikely to be affected as the final report will be an aggregated data without any identifiers.

Condition 5: Is it true that the research cannot be conducted if the waiver is not obtained?
Answer yes or no, and explain why a waiver is indispensable to the research if this is the case.
Yes, the research will not be conducted if the waiver is not obtained as there should be an approval to access the patients' medical records.

Condition 6: Will any individual, family or community be placed at social, psychological, legal or economic risk of harm by the research (if the waiver is approved)?
Answer yes or no, and explain the possible risks to individuals, family and community if the waiver is approved and the data used as intended.
No, there will be no social, psychological or economic risk of ham for any individual, family or community.

Supervisor/Researcher Signature		Student Signature	
Date	18/9/2020	Date	16/09/2019

Appendix 3: UJ Higher Degrees CommitteeApproval

FACULTY OF HEALTH SCIENCES
HIGHER DEGREES COMMITTEE

MPH HDC-01-20- 2020

30 March 2020

TO WHOM IT MAY CONCERN:

STUDENT: **LEBELO, LE**
STUDENT NUMBER: **218100043**

TITLE OF RESEARCH PROJECT: Factors Contributing to High Defaulters for Patients on Antiretroviral Drugs in Berea District; Lesotho

DEPARTMENT OR PROGRAMME: **MASTER OF PUBLIC HEALTH**

SUPERVISOR: **PROF SA FERESU** **CO-SUPERVISOR:** **-**

The Faculty Higher Degrees Committee has scrutinised your research proposal and concluded that it complies with the approved research standards of the Faculty of Health Sciences; University of Johannesburg.

The HDC would like to extend their best wishes to you with your postgraduate studies

Yours sincerely,

Prof S Nalla
Chair: Faculty of Health Sciences HDC
Tel: 011 559 6258
Email: shahedn@uj.ac.za

Appendix 4: UJ Ethical clearance letter

FACULTY OF HEALTH SCIENCES
RESEARCH ETHICS COMMITTEE

NHREC Registration: REC 241112-035

ETHICAL CLEARANCE LETTER
(RECX 2.0)

Student/Researcher Name	Limakatso Lebelo	Student Number	218100043
Supervisor Name	Prof S Feresu		
Department	Environmental Health		
Research Title	FACTORS CONTRIBUTING TO HIGH DEFAULTERS FOR PATIENTS ON ANTIRETROVIRAL DRUGS IN BEREA DISTRICT, LESOTHO		
Date	14 January 2020	Clearance Number	REC-268-2020

Approval of the research proposal with details given above is granted, subject to any conditions under 1 below, and is valid until 2021/01/13.

1. **Conditions:**
Permission/approval from local Research Ethics Committee.

2. **Renewal:**
It is required that this ethical clearance is renewed annually, within two weeks of the date indicated above. Renewal must be done using the Ethical Clearance Renewal Form (REC 10.0), to be completed and submitted to the Faculty Administration office. *See Section 12 of the REC Standard Operating Procedures.*

3. **Amendments:**
Any envisaged amendments to the research proposal that has been granted ethical clearance must be submitted to the REC using the Research Proposal Amendment Application Form (REC 8.0) prior to the research being amended. Amendments to research may only be carried out once a new ethical clearance letter is issued. *See Section 13 of the REC Standard Operating Procedures.*

4. **Adverse Events, Deviations or Non-compliance:**
Adverse events, research proposal deviations or non-compliance must be reported within the stipulated time-frames using the Adverse Event Reporting Form (REC 9.0). *See Section 14 of the REC Standard Operating Procedures.*

The REC wishes you all the best for your studies.

Yours sincerely,

Prof. Christopher Stein
Chairperson: REC
Tel: 011 559 6564
Email: cstein@uj.ac.za

Appendix 5: Local approval NH-REC approval letter

LESOTHO

Ministry of Health
P.O. Box 514
Maseru 100

Category of Review:
[x] Initial Review
[ ] Continuing Annual Review
[ ] Amendment/Modification
[ ] Reactivation
[ ] Serious Adverse Event
[ ] Other _____

REF: ID 02-2020

Date: January 30, 2020
To
Limakatso Lebelo
Student number: 218100043
University of Johannesburg

Dear Ms. Lebelo

RE: Factors Contributing to High Defaulters for Patients on Antiretroviral Drugs in Berea District; Lesotho

This is to inform you that the **Ministry of Health Research and Ethics Committee** reviewed and **APPROVED** the above named protocol and hereby authorizes you to conduct the study according to the activities and population specified in the protocol. Departure from the approved protocol will constitute a breach of this permission.

This approval includes review of the following attachments:
[x] Study Protocol dated 31 October, 2019
[ ] Informed consent form: Informed Consent Waiver Secondary Data (REC 15.0)
[x] **Data Collection:** Data Abstraction Form (Questionnaire)
[x] Participant materials: information letter and consent form (REC11.0)
[x] **Other materials**: letter of permission to conduct a study dated 4th November, 2019, Letter for Maseru DHMT dated 17th January 2020, Curriculum vitae for Lebelo , Ethical Clearance Letter from Research Ethics Committee, Faculty of Health Sciences – University of Johannesburg

This approval is **VALID** until January 30, 2021.

Please note that an annual report and request for renewal, if applicable, must be submitted at least 6 weeks before the expiry date.

All serious adverse events associated with this study must be reported promptly to the MOH Research and Ethics Committee. Any modifications to the approved protocol or consent forms must be submitted to the committee prior to implementation of any changes.

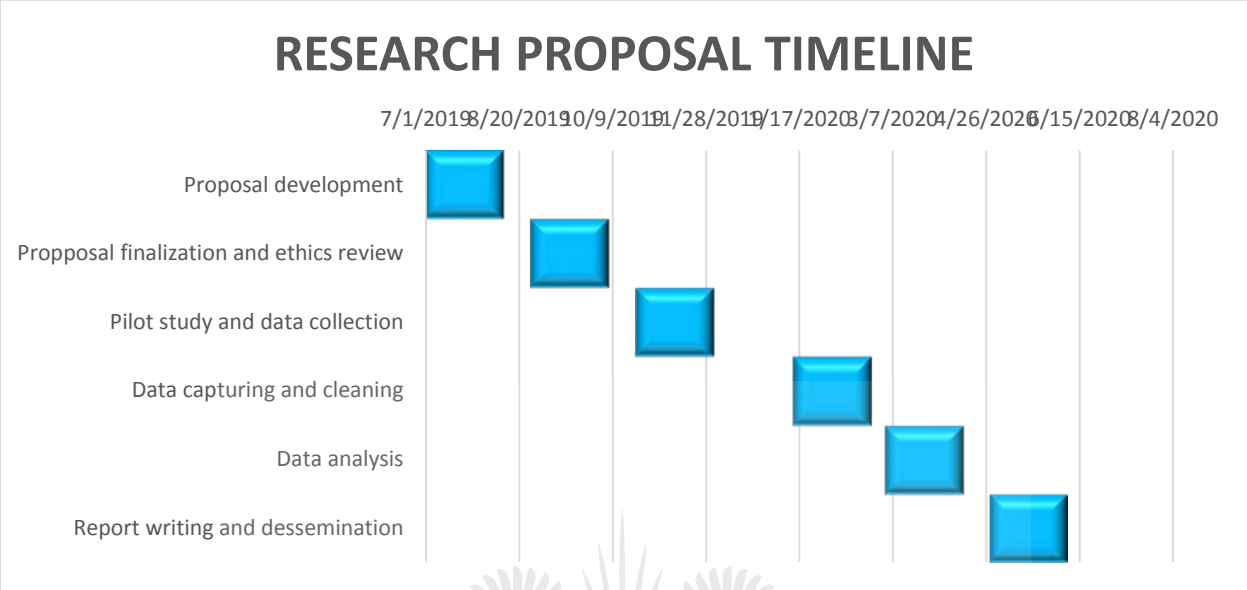
We look forward to receiving your progress reports and a final report at the end of the study. If you have any questions, please contact the Research and Ethics Committee at nounoh@gmail.com (or) 22226317.

Sincerely,

Dr. Nyane Letsie
Director General Health Services

Dr. Limpho Maile
Member of National Health Research
Ethics Committee (NH-REC)

Appendix 6: Timelines



Appendix 7: Budget

Item	Description	Cost estimates
Laptop	A computer for writing and doing all the research work.	LSL 8900.00
Data/ Wi-Fi router	Data for installing the software used in sample calculation and data analysis.	LSL 960.00
Printing	Printing of questionnaires for pilot study and for data collection.	LSL 2375.00
Travel expenses	Transport cost to the study sites for pilot study and data collection.	LSL 2500.00
Communication expenses	Airtime for arranging for pilot study and for conducting participants to administer portion of the questionnaire.	LSL 1500.00
Data analysis	Consultant fee for data analysis.	LSL 2500.00
Filing cabinet	Safety box or filing cabinet to store study documents.	LSL 1500.00
Grand Total		LSL 20,235.00

Appendix 8: Editor Certificate

EDITING/PROOFREADING CONFIRMATION

To whom it may concern,

This serves to certify that I **Mrs Fortune Shonhiwa** has proofread and edited **Limakatso Lebelo's** Masters Dissertation to ensure that the language, grammar, punctuation and spelling are academically sound and appropriate, by rectifying errors, wherever these have been identified, and rephrasing sentences that would possibly make one lose sight of the flow of the argument.

Title of the Dissertation: **FACTORS CONTRIBUTING TO HIGH DEFAULTERS FOR PATIENTS ON ANTIRETROVIRAL DRUGS IN BEREA DISTRICT, LESOTHO**

Editor's name: **Mrs Fortune Shonhiwa**

Qualifications:

MSc: Frostburg State University, USA

MSc: West Virginia University, USA

Signature:

Date: 03 November, 2020

Appendix 9: Turnitin certificate

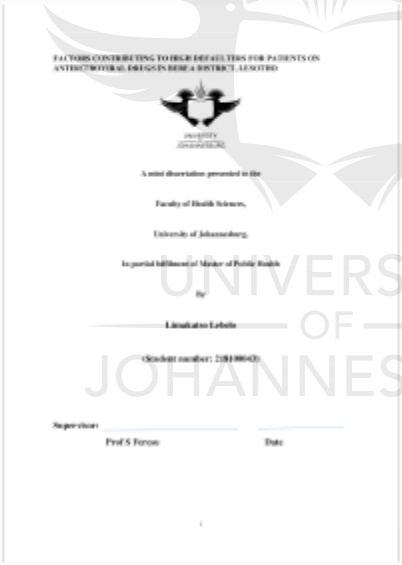
turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	LE LEBELO
Assignment title:	D4 Minor Dissertation I: Turnitin Sub…
Submission title:	Factors contributing to high defaulte…
File name:	Limakatso_Lebelo-MPH_Mini_Disse…
File size:	1.5M
Page count:	72
Word count:	16,688
Character count:	93,348
Submission date:	21-Nov-2020 07:08PM (UTC+0200)
Submission ID:	1365019779



FACTORS CONTRIBUTING TO HIGH DEFAULTERS FOR PATIENTS ON ANTIRETROVIRAL DRUGS IN BEREA DISTRICT, LESOTHO

A mini dissertation presented to the

Faculty of Health Sciences,

University of Johannesburg,

In partial fulfilment of Master of Public Health

By

Limakatso Lebelo

(Student number: 218190943)

Supervisor:

Prof S Feroz Date